

Exhibit 1

1 IN THE UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
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4
5 IN RE: VALSARTAN)
6 LOSARTAN, AND IRBESARTAN)
7 PRODUCTS LIABILITY)
8 LITIGATION)
9)
10) No. 2875
11)
12) HON. ROBERT B. KUGLER
13 This Document Relates to)
14 All Actions)
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24 REPORTED BY: ELAINA BULDA-JONES, CSR 11720
25)

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		Page 6		Page 8
1	Exhibit 7 Valsartan USP Monograph, January 28, 2022	128	1	THE VIDEOGRAPHER: Okay. We are now on
2	Exhibit 8 Impurities in Drug Products and Drug Substances - A USP Approach, Ravi Ravichandran, Principal Scientific Liaison	145	2	the record.
3	Exhibit 9 Overview of USP General Chapters <476> and <1086>, Prescription/Non-Prescription Stakeholder Forum, October 19, 2017	152	3	My name is Kristina Lee. I am a
4	Exhibit 10 FDA's Overview of the Guidance for Industry: Control of Nitrosamine Impurities in Human Drugs, David Keire, Ph.D., and Dongmei Lu, Ph.D., Office of Pharmaceutical Quality, October 2, 2020	156	4	videographer for Golkow Litigation Services.
5	Exhibit 11 E-mail, 06 July 2018, To: All, From: Global Quality Compliance, Re: Lift of Hold Status for All Finished Products Manufactured using Valsartan API from Jubilant and Mylan	165	5	Today's date is February 17th, 2022, and
6	Exhibit 12 Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA	210	6	the time is 7:18 Pacific.
7	Exhibit 13 Orange Book Preface	224	7	This remote video deposition is being held
8	Exhibit 14 Expert: Nitrosamines 'Can Slip Through the Manufacturing Process,' Making Reference Standards Essential to Avoid this Carcinogen in the Drug Supply Chain, June 29, 2021	256	8	in the matter of Valsartan, Losartan and Irbesartan
9	Exhibit 15 Invoices, 5 pages	270	9	Products Liability Litigation, MDL No. 2875, for the
10			10	United States District Court, District of New
11			11	Jersey. The deponent is Roger Williams.
12			12	All parties to this deposition are
13			13	appearing remotely and have agreed to the witness
14			14	being sworn in remotely. Due to the nature of
15			15	remote reporting, please pause briefly before
16			16	speaking to ensure all parties are heard completely.
17			17	All counsel will be noted on the
18			18	stenographic record.
19			19	The court reporter is Elaina Bulda-Jones,
20			20	and she will now swear in the witness.
21			21	ROGER WILLIAMS, M.D.,
22			22	called as a witness by the Plaintiffs herein, being
23			23	first duly sworn by the Certified Shorthand Reporter
24			24	was thereupon examined and testified as is
25			25	hereinafter set forth.
		Page 7		Page 9
1	Exhibit 16 NDA Partners LLC, Curriculum Vitae of Roger Williams, M.D., November 2021	284	1	THE REPORTER: Mr. Stanoch.
2	Exhibit 17 Video	284	2	MR. STANOCH: Thank you.
3	Exhibit 18 Complete set of materials sent to Dr. Williams	292	3	EXAMINATION
4			4	BY MR. STANOCH:
5			5	Q. Good morning, Dr. Williams.
6			6	A. Good morning, Mr. Stanoch.
7			7	Q. Could you tell us where you are located
8			8	today?
9			9	A. I'm in San Francisco, California, in 4
10			10	Embarcadero Center in the offices of Greenberg
11			11	Traurig.
12			12	Q. Thank you.
13			13	And other than Teva's counsel, Ms. Lockard
14			14	and Mr. Harkins, and perhaps any tech people, are
15			15	there anybody else in the room with you?
16			16	A. No, there are not.
17			17	Q. Other than a box which we have yet to open
18			18	of potential documents that we sent to your counsel,
19			19	do you have any documents with you in your room?
20			20	A. I see three documents that my counsel has
21			21	put before me. One is the report, one is the
22			22	materials considered, and one is the deposition
23			23	request.
24			24	Q. Perfect. Anything else?
25			25	A. I have a blank pad of paper and a pen, and

<p>1 nothing else.</p> <p>2 Q. Thank you.</p> <p>3 Now, you have been deposed a number of</p> <p>4 times before; is that fair?</p> <p>5 A. That's true, Mr. Stanoch.</p> <p>6 Q. Right. So you understand the general</p> <p>7 rules we will be following here today, that I will</p> <p>8 be asking you a series of questions, you'll be</p> <p>9 providing answers, everything everyone says on the</p> <p>10 record will be taken down by the stenographer and on</p> <p>11 the video; you understand that?</p> <p>12 A. I do.</p> <p>13 Q. Right. And if you do not understand the</p> <p>14 question, I ask, please tell me; otherwise I will</p> <p>15 assume you understand; is that fair?</p> <p>16 A. That's fair.</p> <p>17 Q. Do you understand you should answer the</p> <p>18 question unless your counsel instructs you</p> <p>19 otherwise?</p> <p>20 A. I do understand that.</p> <p>21 Q. Is there any reason why you cannot testify</p> <p>22 truthfully and accurately today?</p> <p>23 A. There is no reason.</p> <p>24 Q. Excellent. Let's do some housekeeping</p> <p>25 with exhibits, Dr. Williams. First, before we get</p>	<p>Page 10</p> <p>1 correct?</p> <p>2 A. Yes, I do, Mr. Stanoch.</p> <p>3 Q. Very good. And as a housekeeping matter,</p> <p>4 Dr. Williams, could you tell us what revisions were</p> <p>5 made in the copy of your report that we have marked</p> <p>6 as Exhibit 1 over the report that was originally</p> <p>7 provided on January 12th, 2022?</p> <p>8 A. Yes. There were two references that</p> <p>9 needed to be changed.</p> <p>10 One was a reference to a guidance of FDA</p> <p>11 that talks about drug substances for ANDAs. In the</p> <p>12 unrevised report, that was not provided, so we have</p> <p>13 now provided that guidance. And it's listed in the</p> <p>14 materials considered as well as cited in my report.</p> <p>15 And I'll be glad to answer questions about that</p> <p>16 guidance if you wish, Mr. Stanoch.</p> <p>17 The other change was a reference to a USP</p> <p>18 guidance that talks about submitting requests for</p> <p>19 revisions to the United States Pharmacopeia-National</p> <p>20 Formulary. And the reason for the change was when I</p> <p>21 looked at it recently, it spoke to requests for</p> <p>22 revisions of dietary supplements, which of course is</p> <p>23 not pertinent in this matter. So we changed it to</p> <p>24 requests for revisions for chemical substances, and</p> <p>25 that is now referenced in the revised report and</p>
<p>Page 11</p> <p>1 going, I am going to mark as Williams 1 the revised</p> <p>2 expert report that your counsel provided to us 20 or</p> <p>3 so minutes ago.</p> <p>4 MR. STANOCHE: Stand by, everyone.</p> <p>5 (Whereupon, Exhibit 1 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. STANOCHE:</p> <p>8 Q. So, Dr. Williams, the copy of your report</p> <p>9 in front of you given to you by your counsel, we</p> <p>10 will call that Exhibit 1, and for everyone else's</p> <p>11 benefit, it's available as Exhibit 1 on the</p> <p>12 electronic shared files. Are you good with that,</p> <p>13 Doctor?</p> <p>14 A. I am.</p> <p>15 Q. Excellent. I am going to mark also the</p> <p>16 revised list of the materials you considered that</p> <p>17 your counsel also provided a little earlier this</p> <p>18 morning. Stand by.</p> <p>19 (Whereupon, Exhibit 2 was marked for</p> <p>20 identification.)</p> <p>21 BY MR. STANOCHE:</p> <p>22 Q. Exhibit 2, Dr. Williams, that's the list</p> <p>23 of materials considered that were provided to us 20</p> <p>24 or so minutes ago. You have a physical copy in</p> <p>25 front of you, I understand, from your counsel,</p>	<p>Page 12</p> <p>1 also in the materials considered. Again, I'll be</p> <p>2 glad to answer questions about that document if you</p> <p>3 wish, Mr. Stanoch.</p> <p>4 And then there were two additional</p> <p>5 documents that were important to my report relating</p> <p>6 to the Orange Book, and those were not listed in the</p> <p>7 materials considered, so we adjusted the materials</p> <p>8 considered to include those references. One was an</p> <p>9 Orange Book from January 2019 summarizing the prior</p> <p>10 year, 2018. And then the other Orange Book</p> <p>11 reference was the Orange Book Supplement No. 8,</p> <p>12 August for 2018, and those are both referenced in my</p> <p>13 report and also now listed in the materials</p> <p>14 considered.</p> <p>15 Q. Okay. Thank you, Doctor.</p> <p>16 And regarding your report first, I believe</p> <p>17 the particular footnotes that were updated with the</p> <p>18 two materials you noted, those are Footnotes 20 and</p> <p>19 21 of page 17 of your report; is that right?</p> <p>20 A. Let me take a quick look just to confirm.</p> <p>21 Yes, you have it exactly right, Mr. Stanoch.</p> <p>22 Q. Very good. And the materials considered,</p> <p>23 the two Orange Book references that are now listed</p> <p>24 in your revised materials considered, I believe it's</p> <p>25 your testimony that you had relied on them in</p>

<p>1 preparing your report, they just didn't make it into 2 the reliance materials initially; is that fair? 3 A. Yes, the materials considered listing. 4 But they were referenced in my report appropriately 5 and cited. 6 Q. Understood. And do you happen to have the 7 page of the reliance materials where the two Orange 8 Book sources are now listed? 9 A. I'm sure I do, but it might help me if we 10 agree on what page that is. 11 Q. I think it may be page 2, but if you 12 cannot do it quickly, Doctor, we can certainly take 13 care of it at a break. I don't think there is a 14 controversy on this. 15 A. Oh, yeah, there it is. It's under 16 "Regulatory Guidances, Standards, and Documents," 17 and there is a 2019 Orange Book, which is the second 18 listing in that category, and then the 2018 Orange 19 Book, Cumulative Supplement 8, August 2018, which is 20 the third listing. 21 MR. HARKINS: Did we lose Mr. Stanoch? 22 THE WITNESS: Oh, I think he is looking at 23 the materials considered. 24 (Whereupon, a brief discussion off the 25 record.)</p>	<p>Page 14</p> <p>1 Mr. Stanoch, with today's date. 2 Q. Understood. Other than the two footnote 3 revisions we discussed and the new signature page, 4 are there any other changes in your report, now 5 dated February 17th, 2022, over the original 6 iteration of your report from January 12th, 2022? 7 A. No, there are not. 8 Q. Okay. And on your lists of materials 9 considered, I think there were a few other things 10 that were added between your original lists from 11 January 12th and today besides the two Orange Book 12 sources. And do you recall that generally, sir? 13 A. No, actually I can't say I do, 14 Mr. Stanoch. 15 Q. That's fine. And, you know, for instance, 16 if you look at page 1 of Exhibit 2, your latest 17 iteration of materials considered, there is now a 18 section that says, "Defendants' Expert Reports (with 19 exhibits)." Do you see that? 20 A. Page 1? Oh, yes, I do see that. 21 Q. Right. And the first line is the report 22 of Timothy Anderson. Do you see that? 23 A. I do see that. 24 Q. And then it continues on, correct? 25 A. Yes.</p>
<p>1 THE VIDEOGRAPHER: Okay. We're going off 2 the record. The time is 7:29. 3 (Whereupon, a brief recess was taken.) 4 THE VIDEOGRAPHER: Okay. We're coming 5 back on the record. The time on the video monitor 6 is 7:37. Please begin. 7 BY MR. STANOCHE: 8 Q. Okay. Doctor, thank you for bearing with 9 us with the technical issues. I believe we were 10 just looking at your revised reliance materials, 11 correct, that's where we were? 12 A. Yes, I understand. 13 Q. Uh-huh. And you were showing us, you 14 know, the two Orange Book sources that are now 15 listed under the "Regulatory Guidances" heading, I 16 believe it was, right? 17 A. Yes. 18 Q. All right. Other than the updates of 19 Footnotes 20 and 21 of your report, does the revised 20 report that's been produced today have any other 21 changes to it over your original January 12th, 2022, 22 report? 23 A. No, it does not. 24 Q. Okay. Thank you. 25 A. There is a new signature page,</p>	<p>Page 15</p> <p>1 Q. And you could say it in your own words, 2 but it looks like your revised materials here of 3 2/17/2022 is showing that you have now reviewed all 4 of the other defense expert reports listed here, 5 whereas you had not reviewed them at the time you 6 rendered your original report of January 12th, 2022; 7 is that right? 8 A. Yes. I think I did not see these expert 9 reports before I concluded my January 12th report. 10 Q. Uh-huh. Okay. And so the -- 11 MS. LOCKARD: And just for the record, 12 Dave, the list updating the list of materials with 13 the new expert report was included in the 2/15 14 production. So just, I think, to clarify, you have 15 received -- prior version that did have the expert 16 reports listed. 17 MR. STANOCHE: No, I agree, Counsel. And 18 this isn't controversial. It's just more 19 housekeeping. 20 MS. LOCKARD: Right. 21 BY MR. STANOCHE: 22 Q. But I just wanted to establish, 23 Dr. Williams, that as of the date of your original 24 January 12th, 2022, report, you had not reviewed any 25 defense expert reports in this case, right?</p> <p>Page 17</p>

<p>1 A. That's true.</p> <p>2 Q. And since then, you did review them all at</p> <p>3 some point, correct?</p> <p>4 A. Well, what I would say --</p> <p>5 MS. LOCKARD: Objection. Form.</p> <p>6 THE WITNESS: -- is I looked at all of</p> <p>7 them, and some of them I looked at more carefully</p> <p>8 than others.</p> <p>9 MS. LOCKARD: All of them on the list.</p> <p>10 THE WITNESS: All of them on the list,</p> <p>11 yes.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. And because you looked at the defense</p> <p>14 expert reports on the list we're looking at in</p> <p>15 Exhibit 2 after you issued your original report, is</p> <p>16 it fair to say that you did not rely on any defense</p> <p>17 expert report in rendering your January 12th, 2022,</p> <p>18 opinions?</p> <p>19 A. That's accurate, Mr. Stanoch. Thank you.</p> <p>20 Q. Right. And further, because you only</p> <p>21 noted two changes, to Footnotes 20 and 21, in your</p> <p>22 report dated today, did anything in the defense</p> <p>23 expert reports listed here in Exhibit 2 alter or</p> <p>24 change your opinions as they were originally</p> <p>25 expressed in your January 12th, 2022, report?</p>	<p>Page 18</p> <p>1 original January 12th report to your February 17th</p> <p>2 report, right?</p> <p>3 A. No, I have not changed my opinions at all.</p> <p>4 Q. Very good. Thank you, Doctor. Let's put</p> <p>5 that aside, and if there is other sort of</p> <p>6 housekeeping things with the reliance materials, we</p> <p>7 can hit it later, okay?</p> <p>8 A. Thank you.</p> <p>9 Q. So, Doctor, your report -- and we will use</p> <p>10 Exhibit 1, which is the one dated February 17th,</p> <p>11 2022, this report includes all opinions you are</p> <p>12 currently offering in this matter, correct?</p> <p>13 A. Yes.</p> <p>14 Q. At this time, do you intend to offer any</p> <p>15 other opinions in this matter besides those</p> <p>16 reflected in your report, Exhibit 1?</p> <p>17 A. No.</p> <p>18 MS. LOCKARD: I'm going to object to that,</p> <p>19 as it calls for attorney work product. Obviously we</p> <p>20 reserve the right to use Dr. Williams in the</p> <p>21 liability portion and for liability opinions, but he</p> <p>22 is not intending to give those opinions today.</p> <p>23 Court Reporter, can you hear me?</p> <p>24 THE REPORTER: Yes, ma'am.</p> <p>25 MR. STANOCH: I heard you too,</p> <p>Page 20</p>
<p>1 A. No, nothing at all.</p> <p>2 Q. It also appears, Doctor, looking at</p> <p>3 Exhibit 2, your reliance materials list of today,</p> <p>4 page 2, you see "Deposition Transcripts"? Do you</p> <p>5 see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. All right. And I believe you now list</p> <p>8 four entries there, beginning with, "Transcript of</p> <p>9 Edward Kaplan," through "Transcript of Ron Najafi</p> <p>10 Deposition"; do you see those four entries?</p> <p>11 A. I do.</p> <p>12 Q. Right. And those were not listed in your</p> <p>13 original reliance materials in January 12th, 2022,</p> <p>14 right, because these transcripts postdated your</p> <p>15 report; is that fair?</p> <p>16 A. Exactly. You can see that from the date</p> <p>17 in the first part of each entry.</p> <p>18 Q. Absolutely right. And my only point is</p> <p>19 going to be, Doctor, is that you did not rely on the</p> <p>20 transcripts of Edward Kaplan, Kali Panagos, John</p> <p>21 Quick or Ron Najafi in rendering your January 12th,</p> <p>22 2022, opinions, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And nothing in those four transcripts have</p> <p>25 led you to change or alter your opinions from your</p>	<p>Page 19</p> <p>1 Ms. Lockard.</p> <p>2 MS. LOCKARD: Okay.</p> <p>3 MR. STANOCH: I had nothing to respond to.</p> <p>4 MS. LOCKARD: Okay. No problem. I just</p> <p>5 didn't see it come up on the realtime, so I thought</p> <p>6 maybe we had lost someone, but I see it now.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Doctor, you reference, you know, this</p> <p>9 litigation by caption in Paragraph 2 of your report,</p> <p>10 right?</p> <p>11 A. I'm looking at Paragraph -- "I make this</p> <p>12 disclosure," is that what you are talking about,</p> <p>13 Mr. Stanoch?</p> <p>14 Q. Yes, sir. Yes, sir.</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. And what is your understanding, generally,</p> <p>17 of this litigation, sir?</p> <p>18 A. It relates to the presence of nitrosamine</p> <p>19 impurities, in terms of my report, in Tab 4, ANDAs</p> <p>20 that were approved by FDA for Teva. And there are</p> <p>21 of course many ramifications to that statement, but</p> <p>22 I'll stop there in terms of what my report focuses</p> <p>23 on.</p> <p>24 Q. And you can look at your reliance</p> <p>25 materials, Doctor, but I believe you did not review</p> <p>Page 21</p>

<p style="text-align: right;">Page 22</p> <p>1 any plaintiff-specific discovery materials, did you?</p> <p>2 A. I'm not sure I understand your question.</p> <p>3 Can you point out what you are talking about on my</p> <p>4 materials-considered list?</p> <p>5 Q. Sure. You did not review any transcripts</p> <p>6 of any plaintiffs in this litigation, correct?</p> <p>7 A. As part of my report?</p> <p>8 Q. Correct.</p> <p>9 A. Yes, I was speaking particularly in my</p> <p>10 report about the expert report of Dr. Panagos,</p> <p>11 Mr. Quick, and Dr. Najafi. But as I already said, I</p> <p>12 did not rely on the transcript of the deposition to</p> <p>13 inform my opinions. I was looking more at their</p> <p>14 expert reports.</p> <p>15 Q. Understood, Doctor. You did not review</p> <p>16 any transcripts of depositions taken of any</p> <p>17 plaintiff, as opposed to a plaintiff expert, in this</p> <p>18 litigation, correct?</p> <p>19 A. You know, plaintiffs' expert reports, I'm</p> <p>20 looking at my materials considered, and I think the</p> <p>21 answer to that question is yes. I did not review</p> <p>22 plaintiffs' depositions.</p> <p>23 Q. Okay. You did not --</p> <p>24 A. If I am answering -- yeah. If I am</p> <p>25 answering your question correctly, Mr. Stanoch.</p>	<p>1 but I wouldn't be able to safely say it was --</p> <p>2 Mr. Stanoch, does that help?</p> <p>3 BY MR. STANOCHE:</p> <p>4 Q. Well, again, Dr. Williams, this is not</p> <p>5 trying to be a gotcha. I don't see in your reliance</p> <p>6 materials, for example, any Bates number for a</p> <p>7 document that a plaintiff produced the documents.</p> <p>8 And I just want to confirm, then, you did not look</p> <p>9 at any documents that were Bates-stamped as being</p> <p>10 produced from plaintiffs.</p> <p>11 A. I think I can agree with that unless my</p> <p>12 counsel wishes to object.</p> <p>13 MS. LOCKARD: No. I assume you are</p> <p>14 talking about discovery documents. And obviously</p> <p>15 there are plaintiff pleadings and disclosures and</p> <p>16 then whatnot on the list, but --</p> <p>17 MR. STANOCHE: Yes, that's right. And my</p> <p>18 questions were about discovery materials, Counsel,</p> <p>19 you know, right. Right.</p> <p>20 Q. And, Dr. Williams, again, so you did not</p> <p>21 review, for example, copies of individual plaintiff</p> <p>22 pharmacy records that any given plaintiff might have</p> <p>23 produced, right? You don't recall seeing any of</p> <p>24 that, right?</p> <p>25 A. No, you are correct, Mr. Stanoch.</p>
<p style="text-align: right;">Page 23</p> <p>1 Please help me if you think I didn't.</p> <p>2 Q. No, this is not a trick question,</p> <p>3 Dr. Williams. I agree with you that nowhere in your</p> <p>4 reliance materials do you list transcripts of</p> <p>5 depositions taken of a plaintiff, as opposed to a</p> <p>6 plaintiff expert, so I just wanted to make sure my</p> <p>7 understanding was correct. And it sounds like we</p> <p>8 are in accord, right?</p> <p>9 A. Yes. Yes. I think we're in agreement</p> <p>10 now. One of the reasons I was struggling, I was</p> <p>11 trying to look for something that wasn't on the</p> <p>12 list, and that's a little difficult.</p> <p>13 Q. Of course. And you did not review any</p> <p>14 documents produced by any plaintiff in this</p> <p>15 litigation, correct?</p> <p>16 MS. LOCKARD: And I'll just make the</p> <p>17 objection that I'll say it's vague and confusing</p> <p>18 because I don't know that Dr. Williams knows who</p> <p>19 produced what. But, I mean, I don't want to answer</p> <p>20 the question for him, but --</p> <p>21 THE WITNESS: Well, yeah, I think</p> <p>22 Ms. Lockard is stating it correctly. I don't know</p> <p>23 what was produced by plaintiffs. But I find it hard</p> <p>24 to believe that they wouldn't have produced some of</p> <p>25 the material that also came to me from my counsel,</p>	<p>1 Q. Right. And you don't recall ever</p> <p>2 reviewing any medical records that a particular</p> <p>3 plaintiff might have produced in this litigation,</p> <p>4 correct?</p> <p>5 A. I did not.</p> <p>6 Q. Uh-huh. And you don't recall reviewing</p> <p>7 any insurance materials that any particular</p> <p>8 plaintiff might have produced in this litigation,</p> <p>9 correct?</p> <p>10 A. I did not.</p> <p>11 Q. Uh-huh. Do your opinions in this case</p> <p>12 depend on the number of the potential plaintiffs in</p> <p>13 the litigation?</p> <p>14 A. No.</p> <p>15 Q. Right. If this litigation involved one</p> <p>16 plaintiff or 10,000 plaintiffs, your opinions as</p> <p>17 expressed in your report would be the same, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Were you asked to assume by counsel</p> <p>20 anything for purposes of your report, sir?</p> <p>21 A. No, I was not.</p> <p>22 Q. Were you asked to assume that Teva's</p> <p>23 finished-dose valsartan products contained any</p> <p>24 nitrosamines?</p> <p>25 A. Was I asked to make that assumption? No,</p>

<p>1 I was not asked to make that assumption.</p> <p>2 Q. Do you have any opinion on whether Teva's</p> <p>3 finished-dose products did contain nitrosamines?</p> <p>4 MS. LOCKARD: Outside the scope of his</p> <p>5 report. Objection.</p> <p>6 THE WITNESS: My understanding is that FDA</p> <p>7 asked Teva to test some samples of their finished --</p> <p>8 of their drug product manufactured under the four</p> <p>9 ANDAs and that Teva did supply that information to</p> <p>10 FDA. But it's not something I cited to in my</p> <p>11 report.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Uh-huh. So you don't know one way or the</p> <p>14 other whether Teva's finished-dose valsartan</p> <p>15 products contained nitrosamines?</p> <p>16 MS. LOCKARD: Objection. Vague.</p> <p>17 I think if you want to ask him if he has</p> <p>18 personal knowledge, that would be a better question.</p> <p>19 THE WITNESS: Well, in any case, I do</p> <p>20 recall seeing some numbers that Teva provided to</p> <p>21 FDA, but they are not in my report and I don't</p> <p>22 recollect them now.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Uh-huh. And you are not opining, are you,</p> <p>25 Doctor, on the levels of nitrosamines that may or</p>	<p>Page 26</p> <p>1 impurity. After approval, it depends on a number of</p> <p>2 factors, including -- I'm sorry, Mr. Stanoch. Were</p> <p>3 you asking generally about impurities, genotoxic</p> <p>4 impurities, or nitrosamine impurities?</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Potential genotoxic impurities generally,</p> <p>7 not specific to nitrosamines at this question.</p> <p>8 A. Okay. Good. I would say after approval,</p> <p>9 if such an impurity is discovered, I think there</p> <p>10 would be an attempt to work with FDA for a marketed</p> <p>11 drug in the United States to determine what the</p> <p>12 limit should be and what corrective action should</p> <p>13 need to be taken.</p> <p>14 Q. Uh-huh. Should a API manufacturer who</p> <p>15 becomes aware of a potential genotoxic impurity in</p> <p>16 API notify their customers who buy that API?</p> <p>17 MS. LOCKARD: Objection. Outside the</p> <p>18 scope of Dr. Williams' class-certification report</p> <p>19 opinions and gets into the liability issue.</p> <p>20 THE WITNESS: Well, I'm thinking of the</p> <p>21 specific example in this matter where, yes, you</p> <p>22 know, the API manufacturer did inform customers. So</p> <p>23 I would say that is a good practice in my personal</p> <p>24 opinion.</p> <p>25</p>
<p>Page 27</p> <p>1 may not have been in Teva's finished-dose products,</p> <p>2 correct?</p> <p>3 A. No, I'm not.</p> <p>4 Q. Uh-huh. Were you asked to assume by</p> <p>5 counsel that Teva's finished-dose products did not</p> <p>6 contain nitrosamines?</p> <p>7 A. No, I was not.</p> <p>8 Q. Uh-huh. Were you asked to assume that</p> <p>9 Teva had no knowledge about the chemical synthesis</p> <p>10 processes necessary to create valsartan API?</p> <p>11 A. I was not asked to make that assumption.</p> <p>12 Q. Okay. Right. You were not asked to make</p> <p>13 any assumptions in rendering your opinions, correct?</p> <p>14 A. Yes, that's correct.</p> <p>15 Q. Okay. When an API manufacturer becomes</p> <p>16 aware of a potential genotoxic impurity, sir, what</p> <p>17 should they do?</p> <p>18 MS. LOCKARD: Objection. Form. Outside</p> <p>19 the scope -- his report and the class-certification</p> <p>20 phase.</p> <p>21 THE WITNESS: The way I would answer that,</p> <p>22 Mr. Stanoch, is it depends on when the discovery was</p> <p>23 made. If it is during the development process,</p> <p>24 prior to approval of either the NDA or ANDA, a</p> <p>25 company may be able to mitigate the presence of the</p>	<p>Page 29</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. You mentioned in your answer the API</p> <p>3 manufacturer did inform customers here. What do you</p> <p>4 mean?</p> <p>5 A. Well, if I understand the history in this</p> <p>6 matter, Prinston, which is a company associated with</p> <p>7 ZHP in China, did inform FDA that they were finding</p> <p>8 the NDMA nitrosamine impurity, and I think in turn</p> <p>9 then FDA began working with the various</p> <p>10 manufacturers using the ZHP drug substance.</p> <p>11 Q. Uh-huh. When, to your recollection, did</p> <p>12 ZHP become aware of the potential nitrosamine</p> <p>13 impurities in valsartan API that you alluded to in</p> <p>14 your prior answer?</p> <p>15 MS. LOCKARD: Objection. Speculation.</p> <p>16 THE WITNESS: I think we can look at my</p> <p>17 report.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Sure.</p> <p>20 A. Is it all right if I look at my report</p> <p>21 now, Mr. Stanoch?</p> <p>22 Q. Of course, Doctor.</p> <p>23 A. I would say when this became generally</p> <p>24 known to the public was July 13th, 2018, with the</p> <p>25 first FDA press release. And FDA noted in the press</p>

<p>1 release that their understanding came from Prinston 2 Pharmaceuticals, as I said, which in turn, became 3 aware of the impurity through the efforts of ZHP. 4 And when we are talking about the impurity, we are 5 talking about NDMA.</p> <p>6 Q. Okay. What paragraph are you looking at, 7 Doctor, so we can be on the same page?</p> <p>8 A. It's Paragraph 92.</p> <p>9 Q. Right. And this is the July 13, 2018, 10 reference to an FDA press release about NDMA in the 11 ZHP valsartan API. My question was: When do you 12 recall that ZHP became aware of the NDMA impurity in 13 the valsartan API?</p> <p>14 MS. LOCKARD: Objection. Form. 15 Speculation.</p> <p>16 THE WITNESS: Yes, I don't think I have 17 that information in my report or that I cited to it.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. You don't know when ZHP discovered the 20 potential NDMA impurity in valsartan API?</p> <p>21 MS. LOCKARD: Same objection. Asked and 22 answered as well.</p> <p>23 THE WITNESS: I don't think I stated it in 24 my report, Mr. Stanoch.</p> <p>25</p>	<p>Page 30</p> <p>1 as vague to the extent you are asking about 2 potential genotoxic impurities.</p> <p>3 MR. STANOCH: How would you like me to fix 4 the question, Counsel?</p> <p>5 MS. LOCKARD: Well, if you are asking 6 about nitrosamines, the presence of nitrosamines, 7 that's more specific than potential genotoxic 8 impurities.</p> <p>9 MR. STANOCH: Okay. I withdraw my prior 10 question.</p> <p>11 Q. Doctor, when did Teva become aware of the 12 potential nitrosamine contamination in valsartan 13 API?</p> <p>14 A. It was around the time Teva put on hold 15 the manufacture of its four ANDAs because of the 16 presence of these impurities in the ZHP drug 17 substance.</p> <p>18 Q. Uh-huh. And when --</p> <p>19 A. And that, I believe, was in June of 2018. 20 Then there were a number of activities that Teva 21 undertook, which of course is a core part of my 22 report, but the most important one in terms of my 23 report were the recalls of the products that 24 contained the ZHP drug substance.</p> <p>25 Q. Okay. Should a drug manufacturer such as</p>
<p>1 BY MR. STANOCH:</p> <p>2 Q. Don't you think it would be important for 3 you to know when ZHP became aware of the potential 4 for NDMA impurities in valsartan API in rendering 5 your opinions?</p> <p>6 MS. LOCKARD: Objection. Argumentative.</p> <p>7 THE WITNESS: Remember, I'm speaking to 8 Teva, so, you know, for the most part, I don't focus 9 on ZHP. I'm talking about Teva's actions in the 10 context of the finding of nitrosamine impurities.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Wouldn't you need to know, sir, when ZHP 13 became aware of the NDMA in valsartan API to assess 14 when Teva, as the customer, should have known about 15 that as well?</p> <p>16 A. No, I don't believe so. I think Teva was 17 aware in the weeks before the FDA press release. 18 But again, my focus is on Teva's activities and what 19 they did when they became aware of the presence of 20 nitrosamine impurities in the ZHP drug substance.</p> <p>21 Q. Let's focus on Teva. When did Teva learn 22 of the potential for NDMA genotoxic impurities in 23 valsartan API?</p> <p>24 A. Well --</p> <p>25 MS. LOCKARD: I'm going to object to that</p>	<p>Page 31</p> <p>1 Teva have quality systems in place to ensure that 2 its API suppliers notify them upon the discovery of 3 potential genotoxic impurities?</p> <p>4 MS. LOCKARD: Objection. Outside the 5 scope of the class-certification expert report.</p> <p>6 THE WITNESS: Yes, I did not comment on 7 that in my report. If you are asking me as a 8 personal question, I could say I would think it 9 likely that Teva would have that kind of agreement 10 or understanding.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Uh-huh. Did you undertake to assess 13 whether that agreement or understanding existed here 14 between Teva and ZHP for valsartan API?</p> <p>15 A. No, that was not part of my report or my 16 opinions.</p> <p>17 MS. LOCKARD: Objection. That's outside 18 the scope of the expert report on 19 class-certification issues.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Isn't it a finished-dose manufacturer's 22 responsibility to obtain material information about 23 genotoxic impurities from their API source in a 24 timely manner?</p> <p>25 MS. LOCKARD: Objection. It's liability</p>

<p>1 question. It's outside the scope of the 2 class-classification expert report opinions. 3 MR. STANOCH: Counsel, you have said 4 outside the scope and liability issue a number of 5 times. Could you just -- I'm not picking a fight. 6 I just want to know what you mean by that. 7 MS. LOCKARD: Well, okay. We are in the 8 class-certification phase of the case, correct? 9 There are opinions that are very specific that have 10 been directed by Dr. Williams in his report. These 11 are not liability opinions. 12 The majority of your questions so far this 13 morning have been, what should manufacturers do? 14 What should their quality systems be? And they are 15 all liability opinions, and that is not the 16 substance of his report. That's not within his 17 report. These are squarely liability questions. 18 MR. STANOCH: Well, I appreciate that, 19 Ms. Lockard. I'll just say I don't necessarily 20 agree with you that these are outside the scope of 21 the report that he has issued at class, but I'll 22 note your objection and we can keep going. 23 I'm sorry, Madam Reporter. Would you be 24 kind enough? Did I have a question pending? 25 THE REPORTER: Let me check for you.</p>	<p>Page 34</p> <p>1 The next question: What common evidence 2 would you need to look at to determine whether it is 3 a finished-dose manufacturer's responsibility to 4 obtain important information about genotoxic 5 impurities from their API source in a timely 6 fashion? 7 MS. LOCKARD: Objection. Vague. 8 Confusing. Outside the scope of the 9 class-certification expert report. 10 Did you say common evidence? Or I might 11 have misheard you. 12 THE WITNESS: Are you waiting for 13 Mr. Stanoch to answer, Ms. Lockard? 14 MS. LOCKARD: It's okay. I was, but I 15 have the -- I see on the transcript what he said. 16 All right. I stand by the objection. 17 THE WITNESS: You know, the way I would 18 answer it, Mr. Stanoch, it's a very general 19 question. It's probably more important to focus on 20 nitrosamine impurities because that's what my report 21 focuses on. 22 And all I can say is FDA at many points in 23 this episode said that the finding of these 24 genotoxic nitrosamine impurities was unexpected. So 25 I don't think I can speculate as to when either a</p> <p>Page 36</p>
<p>1 MR. STANOCH: Thank you. 2 (Whereupon, the reporter read the record 3 as follows: 4 "Question: Isn't it a finished-dose 5 manufacturer's responsibility to obtain material 6 information about genotoxic impurities from their 7 API source in a timely manner?") 8 MS. LOCKARD: Same objection. 9 THE WITNESS: You know, the understanding 10 that a drug substance and the corresponding drug 11 product may have genotoxic impurities has been a 12 challenge to FDA and the pharmaceutical industry 13 over many years. The FDA guidance that spoke to how 14 to deal with that actually came out in 2015. 15 So when you ask a general question like 16 that, it's very difficult for me to answer. But 17 definitely if the manufacturer of a drug product 18 feels there could be a genotoxic impurity, there is 19 an obligation to work with FDA to understand that 20 and to limit it if necessary. 21 I hope that's responsive to your question, 22 Mr. Stanoch. 23 BY MR. STANOCH: 24 Q. Partially, but I appreciate you trying, 25 Dr. Williams. I really do.</p>	<p>Page 35</p> <p>1 drug-substance manufacturer or a dosage-form 2 manufacturer would expect something that was -- or 3 anticipate something that was unexpected. I think 4 it's important to keep in mind that these impurities 5 were unexpected. 6 BY MR. STANOCH: 7 Q. Are you finished, Doctor? 8 A. Yes. 9 Q. Thank you. 10 I may ask you that from time to time, just 11 for the video, to make sure I don't step over you 12 and vice versa; is that okay? 13 A. Yes, no problem, Mr. Stanoch. 14 Q. Thank you. I appreciate your patience 15 there. 16 You said "unexpected" a number of times in 17 your answer there, and we will certainly get to 18 that. But let me -- you said that my question would 19 be different if I asked about nitrosamines versus 20 genotoxic impurities generally, so I'm going to ask 21 you the question differently. 22 Question: What evidence would you need to 23 look at in order to determine whether it is a 24 finished-dose manufacturer's responsibility to 25 obtain important information about nitrosamine</p> <p>Page 37</p>

<p>1 impurities from their API source in a timely 2 fashion?</p> <p>3 MS. LOCKARD: Objection. Vague. 4 Confusing. Outside the scope of the 5 class-certification expert report.</p> <p>6 THE WITNESS: You know, it might be 7 helpful, Mr. Stanoch, to back up a little bit on 8 what are the responsibilities of an ANDA filer in 9 terms of assessing impurities in its drug substance 10 and its drug product.</p> <p>11 The presence of genotoxic impurities I 12 would say doesn't really come up too often in that 13 primary responsibility. So I think you are asking 14 for something that, if I may say so, is not routine 15 as part of the ANDA requirements or recommendations 16 by FDA.</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. Are you saying it's not the responsibility 19 of a drug-product manufacturer to identify potential 20 genotoxic impurities?</p> <p>21 MS. LOCKARD: Objection. Clearly outside 22 the scope of the class-certification opinions in the 23 expert report. It's clearly a liability question.</p> <p>24 MR. STANOCHE: This is his last answer, 25 Counsel.</p>	<p>Page 38</p> <p>1 Q. Was there any industry guidance on 2 genotoxic impurities prior to 2015, Doctor?</p> <p>3 A. I think if we look at my report, I could 4 find reference to other documents that had been 5 produced by FDA or the EMA or in ICH, so -- and 6 those documents preceded the 2015 guidance.</p> <p>7 Q. Do you agree that a drug-product 8 manufacturer is ultimately responsible for the API 9 that it incorporates into its finished-dose product?</p> <p>10 A. Yes, I think that's generally a fair 11 statement, Mr. Stanoch.</p> <p>12 Q. Yeah. So Teva is ultimately responsible 13 for the valsartan API that was in its finished-dose 14 valsartan product, correct?</p> <p>15 A. Yes, I think I can agree with that.</p> <p>16 MS. LOCKARD: Objection. It's vague.</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. And that would include the identification, 19 characterization, testing, and control of any 20 potential genotoxic impurities, correct?</p> <p>21 MS. LOCKARD: Objection. Compound. 22 Vague. Outside the scope of the class-certification 23 expert report.</p> <p>24 THE WITNESS: Well, remember, ZHP and Teva 25 are working according to FDA requirements that speak</p>
<p>1 Q. Go ahead, Mr. Williams.</p> <p>2 A. What I would say, Mr. Stanoch, is, you 3 know, the ANDA applicant has a responsibility to 4 look at the impurities in their drug substance and 5 their drug product and decide whether they need to 6 be reported, identified, and qualified. And those 7 are general recommendations that appear in the 8 guidances I cited.</p> <p>9 It was only until 2015 that FDA produced 10 the guidance on how to deal with genotoxic 11 impurities, and that, of course, came to a head 12 three years later with the finding of the 13 nitrosamine impurities.</p> <p>14 So I really can't answer your question 15 about the responsibility of a drug-product 16 manufacturer other than to refer you to that 2015 17 guidance.</p> <p>18 Q. You are saying there was no guidance to 19 the drug industry about genotoxic impurities until 20 2015?</p> <p>21 A. No, I think there were guidances, which I 22 allude to in my report. But the M7 guidance that 23 we're talking about now I think clarified it in 24 terms of how manufacturers need to focus on the 25 possibility of genotoxic impurities.</p>	<p>Page 39</p> <p>1 to identity, strength, quality, purity, and potency.</p> <p>2 When we talk about purity, we're talking about 3 impurities.</p> <p>4 And the guidances that ZHP and Teva would 5 use are the ones I cited in my report, both the ICH 6 Q3A and Q3B with revisions, and then also the 7 corresponding ANDA guidances. None of those 8 guidances mention genotoxic impurities.</p> <p>9 BY MR. STANOCHE:</p> <p>10 Q. Are you saying, then, that Teva had no 11 obligation to potentially identify genotoxic 12 impurities in its finished-dose valsartan products?</p> <p>13 MS. LOCKARD: Objection. Vague. Outside 14 the scope of class-certification expert report.</p> <p>15 THE WITNESS: You know, I think it's clear 16 in my report that FDA gives recommendations in these 17 guidances, and that is what Teva and ZHP would be 18 following to submit their ANDA to FDA for review and 19 approval.</p> <p>20 Now, if FDA had some concern about 21 genotoxic impurities based on the route of synthesis 22 of the drug substance, they could certainly bring 23 that to Teva's attention or the DMF-holder's 24 attention, in this case, ZHP.</p> <p>25 But again, to talk about it generally in</p>

<p>1 terms of responsibility and liability is not 2 something I dealt with in my report. 3 BY MR. STANOCH: 4 Q. Uh-huh. So you are not offering any 5 opinion at this time about which firm would be 6 responsible for the identification of genotoxic 7 impurities in Teva's finished-dose valsartan 8 product? 9 A. I think if there was some reason to 10 suspect the presence of a genotoxic impurity, any 11 drug manufacturer would have to consider that and 12 discuss it with FDA in terms of what to do, but that 13 was not the case here. 14 Q. Uh-huh. Would it be your expectation that 15 Teva would have had systems in place to assure that 16 ZHP would promptly notify it in the event ZHP 17 identified a potential genotoxic impurity in 18 valsartan API? 19 MS. LOCKARD: Objection. Vague. Outside 20 the scope of the class-certification expert report. 21 THE WITNESS: You know, again, you are 22 asking these very general questions, but I would say 23 both ZHP and Teva are sort of marching, if you will, 24 to laws, regulations and guidances that come from 25 FDA, and for the most part those guidances don't</p>	<p>Page 42</p> <p>1 Q. Right. And the paragraph number there is 2 116. Do you see that? 3 A. I do. I do see that. Thank you. 4 Q. Right. Sure. 5 A. And your question about that is? I'm 6 sorry. 7 Q. Yeah, we will get back to that. Let's do 8 this housekeeping. So we scroll back up, that's 9 actually some misnumbering issue. You have another 10 Paragraph 116 starting under "Dr. Najafi's 11 Declaration" on page 38, right? 12 A. Yes, I apologize for these errors. I'm 13 sorry. 14 But I'm sure we can find the part of the 15 report that you want me to talk about. 16 Q. Sure. 17 A. So -- 18 Q. Well, hold on. Hold on. Sure. We could 19 fix. And just to button this up, so then it looks 20 like your paragraph numbering restarts, for the 21 record, on page 44, under the "Rebuttal to 22 Mr. Quick's Expert Declaration." Do you see that? 23 A. Yes, I do. It jumps from 127 and then to 24 110. 25 Q. Right.</p>
<p>1 speak to genotoxic impurities. 2 So if you are talking about a general 3 moral obligation, I could only answer in a personal 4 opinion, but I'm really trying to focus on the 5 regulatory requirements for an ANDA to be considered 6 and, if possible, approved. 7 BY MR. STANOCH: 8 Q. Well, Doctor, you are opining on whether 9 or not Teva followed GMP or proper regulatory 10 practice, I'm looking at Paragraph 116, right? 11 A. 116 speaks to Dr. Najafi's report. Is 12 that where we're looking, Mr. Stanoch? 13 Q. Oh. Well, that might be a separate issue, 14 Doctor. You know, your January 12th report, the 15 numbering -- there is two Paragraph 116s. It went 16 from 116 to 127, and then it restarted at 110. I 17 was looking at your conclusion. Maybe you fixed 18 that in your latest report. Let's take a look. 19 A. I'm sorry for those typo errors. 20 Can you point me exactly to where you are 21 looking, then? Is there a page number? 22 Q. I am looking at page 46, Doctor. 23 A. Okay. Good. 24 Q. And you see the heading "Conclusion"?</p> <p>25 A. Yes, I do.</p>	<p>Page 43</p> <p>1 A. So I think to make sure we're always 2 talking about the right thing, I think if we just 3 give the paragraph number and the page, we should be 4 fine. Would that be all right with you, 5 Mr. Stanoch? 6 Q. Absolutely fine. And, Doctor, was there 7 some cutting-and-pasting issue with the section on 8 your rebuttal to Mr. Quick that messed up your 9 numbering of your paragraphs here? 10 A. No, I would say it was a word-processing 11 error, where you have to sort of back up and make 12 sure that the Word program numbers the paragraph 13 correctly. 14 Q. Sure. I have been there, Doctor. I'm 15 sure we all have. 16 No, did you write this whole section, the 17 "Rebuttal to Mr. Quick's Expert Declaration" in your 18 report? 19 A. I would say, you know, I wrote the report, 20 and I apologize for the limits on my word-processing 21 skills. 22 I did try to correct this. I think we 23 noticed some of the misnumbering when we were 24 looking at drafts, and apparently I failed to do it 25 in the final document.</p>

<p>1 Q. Again, that's totally understandable. I 2 was just getting at -- to say if you wrote this 3 section here, "Rebuttal to Mr. Quick's Expert 4 Declaration," or not?</p> <p>5 A. Yes, I did.</p> <p>6 Q. Uh-huh. And no one gave you that to cut 7 and paste into the report and that messed up your 8 numbering?</p> <p>9 A. No.</p> <p>10 Q. Uh-huh. You said "we" noticed some 11 pagination errors before. Who is the "we" in your 12 answer a couple answers ago?</p> <p>13 A. Well, first of all, it's not a pagination 14 error, it's a paragraph-numbering error. I can tell 15 you exactly how it happens. But I think when we 16 were looking at drafts, one of the counsel pointed 17 out that the numbering was not consistent.</p> <p>18 Q. Okay. Moving on, I'm looking at page 46, 19 your "Conclusions," Doctor. Tell me when you are 20 there.</p> <p>21 A. Okay, Mr. Stanoch, I'm there.</p> <p>22 Q. And the Paragraph 116 on this page, you 23 write in part, "Teva did not fail to follow cGMP or 24 proper regulatory practice." Do you see that?</p> <p>25 A. I do.</p>	<p>Page 46</p> <p>1 learning from ZHP about the NDMA in valsartan API?</p> <p>2 A. You know, you are asking a question that 3 sort of asks me to take your word for it. I don't 4 think I commented on when ZHP or FDA actually 5 informed Teva, but it was certainly in the May, 6 June, July time frame, and I think Teva acted 7 promptly to recall two of its ANDA valsartan 8 products from the U.S. market.</p> <p>9 And that's the way the system is supposed 10 to work. That's what recalls do. It allows the 11 removal of a product that, for one reason or 12 another, needs to be removed from the market, either 13 because it fails GMPs or it fails a specification.</p> <p>14 What is unusual, and I noted this in my 15 report, is the recall occurred before FDA had set a 16 limit on the nitrosamine impurity. So Teva was 17 acting, and I'm going to use FDA words, with what I 18 might call an abundance of caution to remove the two 19 valsartan products manufactured in Malta from the 20 U.S. market.</p> <p>21 Q. Uh-huh. So what I hear you saying is the 22 system worked as it should here.</p> <p>23 ZHP discovered NDMA in valsartan API 24 sometime in the summer of 2018 or shortly before, 25 right?</p>
<p>Page 47</p> <p>1 Q. Right. So you are opining on whether or 2 not Teva followed cGMP and proper regulatory 3 practice, right?</p> <p>4 A. Yes.</p> <p>5 Q. Right. So in the context of your opinions 6 on cGMP and proper regulatory practice, my question, 7 now several questions ago is: Do you believe that 8 Teva was following proper regulatory practice in 9 terms of its relationship with ZHP to ensure that it 10 was promptly notified about potential genotoxic 11 impurities in valsartan API?</p> <p>12 A. I think the answer is yes. I think ZHP 13 was communicating to Prinston, they were 14 communicating with FDA, FDA was communicating with 15 Teva. And Teva promptly recalled all these 16 products, as my report says. So to me, that's the 17 way the system should work.</p> <p>18 And Teva never was under any particular 19 GMP failure notice from FDA. I think FDA was 20 pleased with the way Teva worked out its recalls in 21 order to protect the public when they found out 22 about the nitrosamine impurities. I don't see a 23 failure, Mr. Stanoch. I see success.</p> <p>24 Q. So you are saying, Doctor, that Teva acted 25 reasonably promptly in the summer of 2018 upon</p>	<p>Page 49</p> <p>1 A. Yes, I think you are saying it correctly, 2 Mr. Stanoch.</p> <p>3 Q. ZHP told Teva, correct?</p> <p>4 A. Well, again, I'm not sure of the routes of 5 communication. I think Prinston told FDA and FDA 6 told Teva, and pretty soon everybody is talking 7 about this difficult situation.</p> <p>8 Q. Well, that's fine, whatever your 9 understanding of the route is. So ZHP told its 10 affiliate company, Prinston, right?</p> <p>11 A. If you want to postulate the route of 12 communication, that's fine with me, Mr. Stanoch.</p> <p>13 Q. No, I'm not postulating anything, Doctor. 14 I'm just trying to -- whatever your understanding 15 is, I'm not bickering with it. I'm just trying to 16 make sure I establish what you think the route is, 17 right? So ZHP, we already determined, identified 18 NDMA in valsartan API in 2018, right? We agree with 19 that?</p> <p>20 A. And that information came to Prinston and 21 Prinston brought it to FDA, and then FDA started 22 looking at all the manufacturers of valsartan, and 23 there were several, who used the ZHP product. And 24 that included Teva for two of its four ANDAs.</p> <p>25 Q. So how did the information about the NDMA</p>

<p>1 in 2018 get to Teva?</p> <p>2 A. I would be speculating, but to me, it</p> <p>3 might have come from FDA.</p> <p>4 Q. Well, whatever you think your answer is.</p> <p>5 I'm just trying to see what the telephone route of</p> <p>6 communication is.</p> <p>7 And that's what you were referring to more</p> <p>8 generally as the system working, that the API</p> <p>9 manufacturer passed the information along, and it</p> <p>10 went to the FDA and at some point it got to Teva,</p> <p>11 and then Teva, as you said, instituted its recalls</p> <p>12 for its product that contained the valsartan API,</p> <p>13 right?</p> <p>14 MS. LOCKARD: Objection. Vague.</p> <p>15 Compound. And outside of the scope to the extent</p> <p>16 this line of questioning is asking about what ZHP</p> <p>17 did or should have done.</p> <p>18 THE WITNESS: Yeah, I don't want to get</p> <p>19 into the details of the way you described the routes</p> <p>20 of communication, but I can certainly say that when</p> <p>21 these things come up, everybody needs to talk to</p> <p>22 everybody, including FDA, and FDA is the one that</p> <p>23 prompted Teva to make the recalls.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Yeah, right. You opine that FDA asked</p>	<p>Page 50</p> <p>1 a page number. But yes, your Exhibit 1, page 36,</p> <p>2 Paragraph 109. It begins, "Somewhat unusual,"</p> <p>3 right?</p> <p>4 A. Yes. Yes. We are in the same place,</p> <p>5 Mr. Stanoch.</p> <p>6 Q. Perfect. And you wrote, "the FDA asked</p> <p>7 for recalls of drug products"; do you see that?</p> <p>8 A. Yes. I do see that. And I think that</p> <p>9 corresponds with what I said previously.</p> <p>10 Q. Right, right, right. Well, you were</p> <p>11 saying that FDA and Teva were talking previously,</p> <p>12 but you write in your report that FDA asked for the</p> <p>13 recalls, right?</p> <p>14 A. Well, FDA works with the manufacturer to</p> <p>15 make a voluntary recall. I would say the decision</p> <p>16 on the recall is up to the manufacturer.</p> <p>17 Q. Well, that's not what you wrote here in</p> <p>18 Paragraph 109, is it?</p> <p>19 A. You know, I think the way it works is FDA</p> <p>20 wishes a recall, and a manufacturer -- I don't think</p> <p>21 FDA has the authority to compel a recall. So the</p> <p>22 reason I say it's voluntary is it's up to Teva to</p> <p>23 say, yes, we will do this recall at your request,</p> <p>24 and that's what Teva did.</p> <p>25 I don't think we should quibble about, you</p>
<p>Page 51</p> <p>1 Teva to recall its valsartan containing the API from</p> <p>2 ZHP, right?</p> <p>3 A. Well, the recall was voluntary on Teva's</p> <p>4 part, but they certainly worked closely with FDA to</p> <p>5 make sure that FDA was satisfied with the way their</p> <p>6 recall occurred.</p> <p>7 Q. Uh-huh.</p> <p>8 A. And that recall was in, I want to say,</p> <p>9 June of 2018. Wait a minute. I may have the month</p> <p>10 wrong. I'm sorry, Mr. Stanoch. I can check that if</p> <p>11 you wish.</p> <p>12 Q. Well, I'm looking at Paragraph 109 of your</p> <p>13 report, Doctor. Tell me when you are there.</p> <p>14 A. All right. Which paragraph?</p> <p>15 Q. 109.</p> <p>16 A. And I see that on -- can you say the page,</p> <p>17 Mr. Stanoch?</p> <p>18 Q. 37, sir.</p> <p>19 MS. LOCKARD: It starts on 36.</p> <p>20 THE WITNESS: Okay, yes. I see that,</p> <p>21 Paragraph 109 on page 36.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Stand by. Right. Yeah, you know, I have</p> <p>24 the earlier version of your report, not the one</p> <p>25 given to me this morning, so I'm sorry if I'm off by</p>	<p>Page 51</p> <p>1 know, who was actually driving the decision. I</p> <p>2 think it's a joint decision between FDA and Teva,</p> <p>3 but it's a voluntary act on the part of Teva.</p> <p>4 Q. Well, you know, Doctor, I can only ask</p> <p>5 questions about what you opine and write in your</p> <p>6 report, and what you wrote in your report twice in</p> <p>7 this paragraph is about the FDA asking for these</p> <p>8 recalls, correct?</p> <p>9 A. That could well be how a recall occurs,</p> <p>10 FDA finds something and they work with the company</p> <p>11 to execute a recall. But Teva was voluntarily</p> <p>12 making these recalls, and they did so successfully.</p> <p>13 And they kept FDA apprised of what they were doing,</p> <p>14 and FDA agreed with it.</p> <p>15 Q. Well, you don't write here in this</p> <p>16 paragraph or anywhere in your report that Teva went</p> <p>17 to the FDA and said, we're going to recall our</p> <p>18 product, did you?</p> <p>19 A. You know, I stand by the words in the</p> <p>20 document. Are you providing alternate words,</p> <p>21 Mr. Stanoch?</p> <p>22 Q. I'm not providing anything alternate,</p> <p>23 Dr. Williams. I'm focused on your words in</p> <p>24 Paragraph 109 of your report, where you twice say</p> <p>25 the FDA asked for the recalls.</p>

<p>1 A. Yes, I have no problem with FDA asking for 2 recalls. Does that seem a problem in terms of how 3 Teva executed the recall?</p> <p>4 Q. I'm trying to establish based on your 5 words in your report, Doctor, that Teva did not go 6 to the FDA and said, we need to recall our product, 7 rather, the FDA asked Teva to recall the valsartan 8 product, correct?</p> <p>9 A. I'm not going to debate the words with 10 you. I think you are right, Mr. Stanoch, that 11 Teva -- FDA was asking Teva and Teva responded to 12 this request. It was voluntary because I think Teva 13 could have said, no, we're not going to recall. 14 Teva did not do that. They voluntarily recalled. 15 But you are right, Teva initiated the 16 request based on their findings working with ZHP and 17 other manufacturers.</p> <p>18 Q. I'm going to go back to sort of the chain 19 of communication about the NDMA discovery in June 20 2018. So do you think there was any direct 21 communication between ZHP and Teva about the NDMA 22 discovered in June 2018?</p> <p>23 A. Well, I would have to speculate. It may 24 be in my materials considered, but I didn't cite 25 anything in that report, so at this point it would</p>	<p>Page 54</p> <p>1 part of my report. And I'm not a GMP expert, so I 2 very carefully combined my GMP opinions through 3 brief statements in this report.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. That's confusing to me, Doctor, because 6 the conclusion paragraph we were looking at is you 7 are opining that Teva did not fail to follow cGMP or 8 proper regulatory practice, right?</p> <p>9 A. And I base that on my review of 10 inspections of Teva that occurred over the decade of 11 2010 to the present time. Teva did not have GMP 12 issues insofar as FDA was concerned, including GMP 13 issues related to the nitrosamine impurities.</p> <p>14 Q. So the only basis for your opinion that 15 Teva did not fail to follow cGMP or proper 16 regulatory practice is the status of any FDA 17 inspections of Teva finished-dose facilities?</p> <p>18 A. Yes, exactly. And that's where I spent 19 some time in my report, on that inspectional 20 history, and for the most part, I did not see any 21 particular GMP problems that FDA was bringing to 22 Teva's attention.</p> <p>23 Q. So your opinions are not based in any way 24 on Teva's compliance with cGMP or proper regulatory 25 practice vis-à-vis its API suppliers ZHP and Mylan?</p>
<p>Page 55</p> <p>1 be speculative for me to answer. I would be very 2 surprised if ZHP and Teva weren't communicating on 3 this point.</p> <p>4 Q. Okay. Would it be proper regulatory 5 practice for ZHP to be in communication with its 6 customer Teva about the discovery of NDMA in the 7 valsartan API?</p> <p>8 MS. LOCKARD: Object to the extent you are 9 asking him about what ZHP should or shouldn't have 10 done. It's outside the report.</p> <p>11 THE WITNESS: It seems to me, if a 12 drug-substance manufacturer finds an unidentified 13 impurity that is problematic in their drug 14 substance, they would certainly notify their 15 purchasers.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. What cGMP procedures did Teva have in 18 place to assure that ZHP would inform Teva about any 19 genotoxic impurities in APIs that Teva was 20 purchasing?</p> <p>21 MS. LOCKARD: Objection. Vague. Scope.</p> <p>22 THE WITNESS: You know, Mr. Stanoch, we 23 may look for it in my materials considered, but I 24 did not study that to form my opinions, and I don't 25 think I cite anything into that part of my -- any</p>	<p>Page 57</p> <p>1 MS. LOCKARD: Objection. Vague. 2 Confusing.</p> <p>3 THE WITNESS: Yes, I did not explore 4 separate from FDA inspections how Teva's SOPs 5 conform to FDA's requirements on GMPs. That was not 6 part of my report.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Okay. Well, why do you list all Teva's 9 SOPs in your reliance materials, then, Doctor?</p> <p>10 A. There is a huge amount of material in my 11 materials-considered document, and I would say only 12 a small fraction of that was cited in my report, and 13 even that small fraction was voluminous.</p> <p>14 Q. So am I to take it, then, that the 15 materials that you only relied on for your opinions 16 at this stage are the ones quoted in the -- or cited 17 in the body of your report, not all of them listed 18 in your reliance materials?</p> <p>19 A. No, I think if it is cited in my report, 20 it should be listed in my materials-considered list.</p> <p>21 Was that your question, Mr. Stanoch?</p> <p>22 Q. No. My question is a little different, 23 Doctor. You know, you list a lot of stuff in your 24 reliance materials, including Teva's SOPs, but now 25 you are telling me your opinions don't turn on</p>

<p>1 Teva's SOPs as it relates to Teva's relationship 2 with its API suppliers, right? 3 MS. LOCKARD: Objection. Lacks 4 foundation. Vague. Misstates the document. 5 THE WITNESS: Yes, I think I make -- my 6 opinions are clearly stated both at the beginning 7 and at the end of the report and I provide citations 8 to support those opinions, but I certainly didn't 9 get into the adequacy of Teva's SOPs with regard to 10 conformance to FDA's GMPs. That would have been a 11 completely different report. 12 BY MR. STANOCH: 13 Q. So how am I to know from your reliance 14 materials, Doctor, which materials you are relying 15 on, the opinions in the body of your report? 16 A. I think the best way I could answer that, 17 Mr. Stanoch, is to look at the citations in my 18 report, which are also listed in the materials 19 considered. 20 Q. Got it. So -- 21 MS. LOCKARD: Objection to that question 22 because you continue to name the list of materials 23 considered as his reliance materials, which is 24 confusing and vague and lacks foundation. 25</p>	<p>Page 58</p> <p>1 THE VIDEOGRAPHER: Okay. So we're going 2 off the record. The time is 8:42. 3 (Whereupon, a brief recess was taken.) 4 THE VIDEOGRAPHER: Okay. We're coming 5 back on the record. The time on the video monitor 6 is 8:51. Please begin. 7 BY MR. STANOCH: 8 Q. Doctor, just yes/no, did you talk to your 9 counsel during the break? 10 A. Yes, I did. 11 Q. Did you talk to anyone else? 12 A. No, not at all. 13 Q. Did you look at any documents? 14 A. Did we look at any documents? 15 Q. Correct. 16 A. I think there was one document we looked 17 at. 18 Q. What did you look at? 19 A. It was a management document of Teva that 20 went out globally to many scores of people about -- 21 and it's cited in my report -- about the problem 22 with the ZHP drug substance having nitrosamine 23 impurities. 24 Q. Where is that cited in your report? 25 THE WITNESS: Can you tell me where it is</p>
<p>Page 59</p> <p>1 BY MR. STANOCH: 2 Q. So let me make sure I fully understand it, 3 then. So the materials you rely upon to render your 4 opinions reflected in your report are the ones that 5 are cited in the body of the report? 6 A. Yes, I think as a general statement, 7 Mr. Stanoch, that's correct. And as you can see, 8 it's only a small fraction of all the materials 9 listed in the materials-considered document. 10 Q. Okay. So if an item is listed in your 11 materials considered but not cited in the body of 12 the report, you are not relying on that material in 13 rendering your opinions at this time? 14 A. I think I can agree with that. 15 Q. That's fine. It will make the day go 16 faster, Doctor. Again, I just want to make sure 17 we're on the same field. I appreciate that. 18 MS. LOCKARD: So I think we have been 19 going about an hour, if you are at a point in 20 time -- you are changing topics -- 21 MR. STANOCH: That's fine. Doctor, would 22 you like a break? 23 THE WITNESS: That would be very nice, 24 Mr. Stanoch. 25 MR. STANOCH: Let's do it.</p>	<p>Page 61</p> <p>1 in the cited materials? 2 Okay. It's on page 9, and it's Reference 3 9 on page 9, I believe. 4 BY MR. STANOCH: 5 Q. Is that "Notification Letter from 6 Valsartan re" -- sorry. Start over. "Notification 7 Letter from re Valsartan" "update"? 8 MS. LOCKARD: Just to clear it up, it's -- 9 sorry, you're not trying to -- I know you are just 10 trying to figure out which document it is. The 11 document is 565758. 12 THE WITNESS: Yes, and it's Reference 9. 13 There are actually two references in Reference 9, 14 and it's the first that we looked at briefly. 15 BY MR. STANOCH: 16 Q. Why don't you tell me the Bates numbers of 17 the two documents you looked at? 18 MS. LOCKARD: He looked at one document. 19 He is saying there are two documents referenced in 20 Footnote 9. 21 MR. STANOCH: Oh, I'm sorry, Counsel. I 22 thought he was looking at his materials considered. 23 We are looking at his footnote in his report. Thank 24 you. That's helpful. I see it now, thank you. 25 Q. Did that document refresh your</p>

<p>1 recollection about anything you had looked at 2 before?</p> <p>3 A. No. I don't think it's really pertinent 4 to the questioning. I'm glad to ask questions about 5 it if you wish, Mr. Stanoch.</p> <p>6 Q. Sure. I just need to get a copy of it and 7 to share it for all of our colleagues who are 8 remote, so give me one second. Okay. We will mark 9 that document as Williams Exhibit 3.</p> <p>10 (Whereupon, Exhibit 3 was marked for 11 identification.)</p> <p>12 THE WITNESS: And if I -- Mr. Stanoch, may 13 I point out something in the document that was 14 helpful to some of your questions?</p> <p>15 BY MR. STANOCHE:</p> <p>16 Q. Before you do that, let's make sure I have 17 the same document as you. I'm going to share my 18 screen, Doctor. You will see it looks like a -- 19 it's an e-mail from June 21, 2018, Bates No. 565758. 20 Is this the same document you are holding?</p> <p>21 A. Yes, I believe so.</p> <p>22 Q. Great. I'm going to stop sharing now that 23 we're on the same page.</p> <p>24 This is the document you were referring to 25 that you looked at, right?</p>	<p>Page 62</p> <p>1 break, FDA asked for the recall, but Teva 2 voluntarily did the recall, working with FDA and to 3 FDA's satisfaction.</p> <p>4 Q. You think it was appropriate for Teva to 5 wait, as you said, a month later after being told by 6 ZHP about the NDMA impurity, to institute its 7 recalls?</p> <p>8 MS. LOCKARD: Objection to the form of 9 that question. It lacks foundation and it misstates 10 the evidence.</p> <p>11 THE WITNESS: Well, you know, you can 12 imagine, I'm speaking generally, not to anything I 13 said in my report, but this is an incredibly 14 difficult finding, inspecting a company making 15 products all over the globe, including FDA. And of 16 course FDA is a very stringent regulatory authority, 17 so it doesn't surprise me at all that by the time 18 they sorted through the issues, it took about a 19 month to get the product off the U.S. market.</p> <p>20 BY MR. STANOCHE:</p> <p>21 Q. Okay.</p> <p>22 A. And that's what my report says. And at no 23 time was Teva's product ever deemed adulterated or 24 misbranded, and it was always AB-rated. So I think 25 Teva acted with incredible swiftness.</p>
<p>1 A. Yes. And if you look at the four-digit 2 page number ending 5763 --</p> <p>3 Q. Okay.</p> <p>4 A. -- you can see at the top there is a 5 reference to when ZHP informed Teva that "they came 6 to be aware of a previously unknown impurity that 7 may have genotoxic potential," and that was on 8 June 20th, 2018.</p> <p>9 Q. Got it. And it's your opinion that Teva 10 acted appropriately, promptly, after receiving 11 notification from ZHP on June 20th, 2018?</p> <p>12 A. Yes. The way I would say it, if you look 13 further down, where it says "Investigation," "sites 14 to requested to remove any materials or products 15 using Valsartan API from Zhejiang" -- ZHP.</p> <p>16 So to me, you know, this is a very rapid 17 response on the part of Teva to a problem brought to 18 their attention by ZHP. Remember, the date of the 19 e-mail is 6/21 and they are notified by ZHP on 6/20, 20 so I don't think you could have a much more rapid 21 response.</p> <p>22 And then subsequently to this notice, Teva 23 also issued the recall. And I believe that was in 24 July 16th, 2018, so that was about a month later.</p> <p>25 And again, as we discussed before the</p>	<p>Page 63</p> <p>1 And remember, the issue is not could the 2 nitrosamine impurity be there or not. It could be 3 there. It just didn't have a limit. And FDA set 4 that limit in December 2018.</p> <p>5 Q. Uh-huh. Well, nothing stopped Teva from 6 taking its valsartan with ZHP API in it off the 7 market sooner than when the FDA asked, right?</p> <p>8 MS. LOCKARD: Objection. Vague.</p> <p>9 THE WITNESS: No, I think you're asking 10 for sort of a personal opinion. It seemed to me it 11 happened remarkably quickly, Mr. Stanoch. It wasn't 12 anything that was delayed.</p> <p>13 You know, to issue a recall and discuss 14 with the FDA how to do the recall takes some time. 15 So if you ask me, a few weeks, was that unusual, I 16 don't think it was unusual at all.</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. Uh-huh. It's your opinion that this is 19 how it's supposed to happen, right? ZHP became 20 aware of the impurity, looks like they told Teva, 21 and then Teva acted, based on this Exhibit 3, right?</p> <p>22 MS. LOCKARD: Objection. Vague.</p> <p>23 THE WITNESS: Again, it -- I think I'm 24 speaking personally, but I think Teva's activities 25 here were highly responsible and laudatory.</p>

<p>1 BY MR. STANOCH:</p> <p>2 Q. Okay. And would you say that this is an 3 example of -- in your words from prior to the 4 break -- as how the system is supposed to work in 5 terms of notification about the impurity with 6 genotoxic potential finding its way back to Teva?</p> <p>7 A. Yes, I appreciate those words,</p> <p>8 Mr. Stanoch. Thank you.</p> <p>9 Q. And you would expect this to be the case 10 of how it should work for the discovery of genotoxic 11 impurities in API that a manufacturer like Teva is 12 buying generally, right?</p> <p>13 A. Well, that's a very general statement. 14 But I think in terms of the specifics here with a 15 very difficult impurity to identify and measure, 16 which can be there, it just needs a limit, Teva did 17 something quite remarkable. They might --</p> <p>18 Q. If -- I'm sorry. Go ahead.</p> <p>19 A. I'm speculating, but they might have said 20 to FDA, well, let's wait until we figure out what 21 the limit should be, and, you know, they may not 22 have needed to do a recall at all. But they acted 23 highly responsibly at FDA's request.</p> <p>24 Q. Uh-huh. Right. If ZHP came to be aware 25 of a genotoxic impurity earlier than 2018, would you</p>	<p>Page 66</p> <p>1 from the equation is the limits that FDA set in 2 December 2018.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Were there any acceptable limits for 5 nitrosamines in valsartan API as of June 20, 2018?</p> <p>6 A. Not that I'm aware of, no.</p> <p>7 Q. Uh-huh. Right. Nitrosamines were -- 8 there was -- strike that.</p> <p>9 Right. There was no established 10 acceptable limit for nitrosamines in any valsartan 11 products prior to June 2018, correct?</p> <p>12 A. Or any chemically synthesized drug in the 13 U.S. market.</p> <p>14 Q. Right. Because no one expected the 15 nitrosamines to be in them, correct?</p> <p>16 A. You are reiterating what FDA said. This 17 was unexpected.</p> <p>18 Q. Well, unexpected, you say that numerous 19 times in your report, Doctor. We will get back to 20 that.</p> <p>21 But is it your opinion that without the 22 interim guidelines, there were no guidances out 23 there which would have indicated what level of 24 nitrosamines were allowable in valsartan API or 25 finished dose?</p>
<p>1 expect ZHP to inform Teva of that?</p> <p>2 MS. LOCKARD: Objection. Outside the 3 scope of his opinions. He is not here to give 4 liability opinions about ZHP.</p> <p>5 THE WITNESS: Yes, and I don't have any 6 information on that, Mr. Stanoch, and I don't 7 believe I cited anything about that question.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. In your answer a moment ago, you said Teva 10 did something quite remarkable. Is it your opinion 11 that Teva should have allowed their valsartan to be 12 sold on the market while the FDA came up with 13 interim limits?</p> <p>14 A. I think that's a possible conjecture.</p> <p>15 Q. So you are saying Teva could have -- 16 strike that.</p> <p>17 So you are saying Teva could have kept 18 selling its valsartan with the NDMA in it until the 19 FDA came up with interim limits?</p> <p>20 MS. LOCKARD: Objection. Vague. 21 Speculation.</p> <p>22 THE WITNESS: Yeah, I am speculating, but 23 I point out that it was unusual for FDA to ask a 24 recall of an impurity which FDA says can be in a 25 drug product and a drug substance. What was missing</p>	<p>Page 67</p> <p>1 A. That's my understanding.</p> <p>2 Q. Right. So until the FDA caught ZHP, it 3 was okay for any amount of nitrosamines to be in 4 valsartan API; is that what you are saying?</p> <p>5 MS. LOCKARD: Objection to the form of the 6 question. Argumentative.</p> <p>7 THE WITNESS: Yeah, no, I'm not saying 8 that at all, but of course, you are dealing with an 9 impurity which has a presence in food, and sometimes 10 quite high levels. So FDA had just never crossed 11 this bridge, nor had U.S. industry. Now, as a 12 result of the events of the summer of 2018, they 13 have crossed the bridge, so things are better.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. So you are saying until the FDA 16 established acceptable intake limits for 17 nitrosamines, it was okay whatever limit -- strike 18 that.</p> <p>19 You are saying that valsartan API could 20 have nitrosamines in it until the FDA established 21 interim acceptable limits?</p> <p>22 A. Well, that's true now. You can have -- 23 FDA will allow nitrosamine in drug products as long 24 as they are within the acceptable intake limits.</p> <p>25 FDA is not saying that a product needs to have no</p>

<p>1 nitrosamine impurities. That is not true.</p> <p>2 Q. So it's your opinion that a drug</p> <p>3 manufacturer could have had any amount of</p> <p>4 nitrosamines in their drugs prior to the interim</p> <p>5 limits and that did not pose any concern?</p> <p>6 A. I don't believe I said that anywhere in my</p> <p>7 report, but if you can point it out, Mr. Stanoch, I</p> <p>8 would be glad to comment.</p> <p>9 Q. Well, I'm asking you now if that's your</p> <p>10 opinion, Doctor.</p> <p>11 A. You want me to add that to my opinion in</p> <p>12 my report?</p> <p>13 Q. Are you of the view that prior to the</p> <p>14 FDA's establishment of acceptable intake limits for</p> <p>15 nitrosamines, there was no prohibition on the amount</p> <p>16 of nitrosamines that could be in a drug product?</p> <p>17 A. I think you are saying that correctly,</p> <p>18 because FDA didn't know how to measure for it,</p> <p>19 neither did industry. That all had to be worked</p> <p>20 out. And then once you could measure it, then you</p> <p>21 could begin, you know, following the recommendations</p> <p>22 of the 2015 guidance. And FDA did all that and came</p> <p>23 to a limit.</p> <p>24 Now, you are sort of asking the question:</p> <p>25 What happens before you do all that work? And I</p>	<p>Page 70</p> <p>1 Q. Uh-huh.</p> <p>2 A. Time marches on, regulation marches on.</p> <p>3 If you want to go back in the past and say</p> <p>4 everything was awful or not as good as it is now, I</p> <p>5 don't want to say that.</p> <p>6 Q. Well, respectfully, Dr. Williams, things</p> <p>7 in the past were awful for some of the plaintiffs</p> <p>8 who got these drugs with a genotoxic carcinogen in</p> <p>9 it. So we are talking about that today, all right?</p> <p>10 Do you understand that?</p> <p>11 MS. LOCKARD: I'm going to object to that.</p> <p>12 That's not a question --</p> <p>13 MR. STANOCHE: Withdrawn. I will withdraw</p> <p>14 it.</p> <p>15 Q. You understand this case is about in part</p> <p>16 folks who took the drug, and they had nitrosamines</p> <p>17 in it, right?</p> <p>18 A. I do understand that, and I would be loath</p> <p>19 to have an opinion about whether or how people were</p> <p>20 damaged by the presence of those nitrosamines. I'm</p> <p>21 not offering a toxicology or pharmacology opinion.</p> <p>22 Q. Right. And it's your opinion, though,</p> <p>23 that until the FDA established the acceptable intake</p> <p>24 limits -- and when was that? The final guidance</p> <p>25 was, what, February 2021, I believe you say?</p>
<p>Page 71</p> <p>1 guess the answer is, you know, that's how science</p> <p>2 progresses, that's how regulation progresses, and</p> <p>3 we're all the better for it now. I really can't</p> <p>4 speak to the past.</p> <p>5 Q. Well, isn't it incumbent on a drug</p> <p>6 manufacturer to identify potential genotoxic</p> <p>7 impurities in its product?</p> <p>8 A. You know, Mr. Stanoch, you keep asking</p> <p>9 these questions that are very general. Let me point</p> <p>10 out -- I don't know if you consider this germane,</p> <p>11 but let me say in the 1980s, before there was</p> <p>12 analytical technology, there were a whole bunch of</p> <p>13 impurities that neither FDA nor industry could even</p> <p>14 measure. What do you say about that?</p> <p>15 I mean, are drugs more pure now, better</p> <p>16 controlled than they were in the 1980s? And my</p> <p>17 answer to that is yes. No question about it. You</p> <p>18 know, ICH and FDA worked together to bring that</p> <p>19 better control for what I will call usual impurities</p> <p>20 through the ICH documents.</p> <p>21 And then later on, now, FDA came out with</p> <p>22 the guidance in 2015 that extended it to genotoxic</p> <p>23 impurities. And then the nitrosamine brought it all</p> <p>24 to the fore for a particular genotoxic impurity. So</p> <p>25 we're better off now.</p>	<p>Page 72</p> <p>1 A. No, but there were interim limits</p> <p>2 established in December 2018, and those carried</p> <p>3 forward into the guidance that appeared in</p> <p>4 September 2020, with an update in February 2021.</p> <p>5 Q. Uh-huh. So it's your opinion that prior</p> <p>6 to December 2018, a drug can have any amount of NDMA</p> <p>7 in it with no regulatory consequence?</p> <p>8 A. I wouldn't offer that opinion. I think it</p> <p>9 seems like a dangerous opinion to offer, and I'm</p> <p>10 surprised you state it.</p> <p>11 Q. If a drug had 1,000 nanograms of NDMA in</p> <p>12 it in January of 2018, would that be appropriate?</p> <p>13 MS. LOCKARD: Objection. Vague.</p> <p>14 THE WITNESS: You know, I just can't</p> <p>15 comment on those kind of questions. You are getting</p> <p>16 into how does the FDA set limits for certain</p> <p>17 impurities. And, you know, it has to be done</p> <p>18 carefully and in the context of background, food</p> <p>19 impurities that are nitrosamine impurities. I just</p> <p>20 can't answer that question, Mr. Stanoch.</p> <p>21 BY MR. STANOCHE:</p> <p>22 Q. Uh-huh. So you see no problem with a drug</p> <p>23 product that had a thousand nanograms of NDMA in it</p> <p>24 in January 2018?</p> <p>25 A. I didn't offer that opinion.</p>

<p>1 Q. I'm asking you, do you see any issue with 2 a drug having a thousand nanograms of NDMA in it in 3 January 2018?</p> <p>4 MS. LOCKARD: Objection. Vague. Outside 5 the scope of his class-certification report.</p> <p>6 THE WITNESS: You know, and some of it, as 7 you well know, Mr. Stanoch, relates to the amount of 8 drug in the drug product and the duration of dosing. 9 I mean, your hypothesis might be okay for a drug 10 that's just taken once and never taken again as a 11 single oral tablet.</p> <p>12 BY MR. STANOCHE:</p> <p>13 Q. Uh-huh.</p> <p>14 A. I just can't answer your question. There 15 are too many factors that you are not specifying.</p> <p>16 Q. Uh-huh. Uh-huh. So you can't tell me 17 whether it was okay for any valsartan drug to have 18 NDMA in it prior to the interim limits of 19 December 2018?</p> <p>20 MS. LOCKARD: Objection. Vague.</p> <p>21 THE WITNESS: No, I do know that. FDA has 22 said you could have nitrosamine in your drug 23 product. They say that even now. The question is: 24 What are the limits? And, you know, you can read 25 about it in the guidance in terms of daily dose and</p>	<p>Page 74</p> <p>1 THE WITNESS: Yes, I think that's what FDA 2 would say. And remember, there can be many 3 impurities in a drug substance that are below 4 detectable limit that you just never know about. I 5 mean, we're getting into hypotheticals that are 6 beyond my report.</p> <p>7 BY MR. STANOCHE:</p> <p>8 Q. Is it your opinion, sir, that without the 9 interim guidelines, there were no guidances 10 available which would have indicated what levels of 11 nitrosamines could be present in valsartan?</p> <p>12 MS. LOCKARD: Objection. Asked and 13 answered.</p> <p>14 THE WITNESS: Yes, that's my 15 understanding, that those limits came in 16 December 2018 from FDA.</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. Uh-huh. So prior to December 2018, there 19 was no guidance available to the industry about 20 levels of nitrosamines in valsartan?</p> <p>21 MS. LOCKARD: Objection. Asked and 22 answered.</p> <p>23 THE WITNESS: Yes, I -- do you want me to 24 repeat my answer, Mr. Stanoch?</p> <p>25</p>
<p>Page 75</p> <p>1 duration of dose. That's how they come to these 2 limits.</p> <p>3 BY MR. STANOCHE:</p> <p>4 Q. Do you agree that there was no acceptable 5 limit for nitrosamines prior to December 2018?</p> <p>6 A. That's my understanding. The FDA did not 7 have limits for the nitrosamine impurities before 8 December 2018.</p> <p>9 Q. So without an acceptable limit, then the 10 limit is zero, isn't it?</p> <p>11 A. No. No, no. I wouldn't say that at all. 12 I don't know how you come to zero.</p> <p>13 Q. Uh-huh. Well, the purpose of a limit is 14 to say you can have this much of a substance in the 15 drug, right?</p> <p>16 A. Up to the limit.</p> <p>17 Q. Correct. Up to the limit. Right. And so 18 until that limit was determined, you can't have more 19 than zero amount of a substance in it, can you?</p> <p>20 A. No, no, I wouldn't agree with that at all.</p> <p>21 Q. Well, so even without an interim limit, 22 you are saying it was appropriate for a drug to have 23 some amount of nitrosamine in it?</p> <p>24 MS. LOCKARD: Objection. Asked and 25 answered.</p>	<p>Page 77</p> <p>1 BY MR. STANOCHE:</p> <p>2 Q. Please answer the question.</p> <p>3 A. No, my understanding is I don't think 4 there were specified limits for any nitrosamine 5 impurity before December 2018.</p> <p>6 Q. So I'm trying to understand your opinions, 7 Doctor. So if there is not an established limit for 8 a certain substance in a drug, then you can have 9 that substance in the drug?</p> <p>10 MS. LOCKARD: Objection. Vague. Also 11 outside the scope of his expert report for class 12 certification.</p> <p>13 THE WITNESS: Yes, and I'm looking at my 14 opinion where -- if we go to Page 46, where I look 15 at my conclusions, I don't think I speak to the 16 limit in that set of conclusions. But if you think 17 I did, please draw my attention to it, Mr. Stanoch.</p> <p>18 BY MR. STANOCHE:</p> <p>19 Q. Doctor, you reference interim limits 20 throughout your report, don't you?</p> <p>21 A. As provided by FDA in December 2018. I 22 don't speak to them in any other context, just 23 something that came from FDA.</p> <p>24 Q. Uh-huh. So if there is not an established 25 limit for a certain substance in a drug, you are</p>

<p>1 saying that substance can be in the drug, no 2 problem?</p> <p>3 MS. LOCKARD: Objection. Vague. Asked 4 and answered. Outside the scope of the 5 class-certification expert report.</p> <p>6 THE WITNESS: And that really isn't what 7 I'm saying. I would say if somebody found a 8 nitrosamine impurity in their drug product in 2018, 9 they would properly follow the 2015 guidance and try 10 to figure out a limit. But as I point out in my 11 report, FDA did that for the entire industry. They 12 didn't wait for a single manufacturer to do it.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Uh-huh. If a manufacturer found a 15 nitrosamine impurity in their drug product in 2018, 16 they should have properly followed the 2015 guidance 17 to try to figure out a limit, correct?</p> <p>18 A. I think you are saying it correctly. I'll 19 give a little bit more specification to your 20 example. Let's say an NDA applicant who is building 21 an application for consideration by FDA, if they 22 found a nitrosamine impurity, they could follow the 23 2015 guidance and figure out a limit for it and then 24 submit that to FDA, and FDA would review it and say, 25 yeah, that limit is okay, or, no, we want you to do</p>	<p>Page 78</p> <p>1 I'm speculating, that before FDA set limits, an 2 individual company could have done it, and that 3 might have been perfectly okay.</p> <p>4 And even now, I suppose -- company or a 5 consortium of company could try to convince FDA to 6 set higher limits than the ones they set in 7 December 2018. It's all subject to good data and a 8 good scientific review.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Uh-huh.</p> <p>11 A. So I'm not debating what you are saying at 12 all, Mr. Stanoch.</p> <p>13 Q. Good. And I think we can agree, then, 14 that under the ICH M7(R1) guidance from 2015, it 15 would be incumbent on the manufacturer that 16 discovered a genotoxic impurity to attempt to 17 characterize, test it and potentially set limits on 18 its own without regulatory action, correct?</p> <p>19 MS. LOCKARD: Objection. Outside the 20 scope.</p> <p>21 THE WITNESS: Well, I would agree with 22 your statement, except without regulatory action, 23 because whatever the company would do would be 24 subject to FDA review and approval.</p> <p>25</p>
<p>1 something different.</p> <p>2 But in this case, FDA did that work for 3 industry. So I would say industry now doesn't need 4 to figure out their own limits. FDA has done that 5 for them. And that's what is described in the 6 guidance that I cite.</p> <p>7 Q. Uh-huh. And you referenced a 2015 8 guidance. What are you talking about?</p> <p>9 A. I think that's the M7 guidance.</p> <p>10 Q. That's the ICH M7(R1) guidance, correct?</p> <p>11 A. Yes. And I think I do cite that, so it 12 should be in my materials considered.</p> <p>13 Q. No, you do. I'm not -- issuing with that.</p> <p>14 I want to make sure I understood what you meant by 15 2015 guidance in your answer.</p> <p>16 So I understand you are saying the FDA 17 here set limits eventually for nitrosamines. But if 18 a manufacturer had reason to believe its product 19 contained nitrosamines, the appropriate course would 20 have been for them to work towards establishing 21 limits on their own prior to any FDA guidance, 22 correct?</p> <p>23 MS. LOCKARD: Objection. Outside the 24 scope of his class-certification expert opinions.</p> <p>25 THE WITNESS: Yes, I could imagine, and</p>	<p>Page 79</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Fair enough. So then, I guess, to clarify 3 it, we agree, then, that under the ICH M7(R1) 4 guidance from 2015, it would be incumbent on the 5 manufacturer that suspected genotoxic impurity to 6 attempt to characterize it, test it, and potentially 7 set limits for it, and letting the regulatory body 8 know?</p> <p>9 A. And letting the regulatory body see the 10 data and review it and approve it.</p> <p>11 Q. That's fair. Let's take that same 12 situation and say we're talking about an API 13 manufacturer first, okay? You with me?</p> <p>14 A. Okay.</p> <p>15 Q. Okay. Right. Would you agree that under 16 the ICH M7(R1) guidance from 2015, it would be 17 incumbent on an API manufacturer that suspected a 18 genotoxic impurity to attempt to characterize it, 19 test it and potentially set limits for it, not only 20 in connection with the regulatory body, but also 21 customers purchasing that API?</p> <p>22 MS. LOCKARD: Objection. This is getting 23 far outside the scope of his class-certification 24 expert report, Counsel. You are asking him about 25 API manufacturers and their requirements. That's a</p>

<p>1 liability opinion. He hasn't been retained for that 2 issue, and specifically not for ZHP or any API 3 manufacturers.</p> <p>4 THE WITNESS: You know, and I would add, Mr. Stanoch, that if we're going to talk about it, it might be good to put that guidance on the screen and see exactly who it's directed to. Usually, when FDA creates a guidance with recommendations, they identify who it's intended for. And I'll be glad to review that with you if we could sort of find it.</p> <p>11 It did not figure prominently in my report or my opinions because, as I have already noted, FDA did this for industry. I didn't have to look at what an industry drug-substance or drug-product manufacturer would have or should have done.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. We can look at the ICH guidance in a little bit, but sitting here right now, Doctor, is it your view that the ICH M7(R1) guidance applies only to finished-dose manufacturers, not API manufacturers?</p> <p>22 A. No, I wouldn't say that. And if I looked at the nitrosamine guidance, I think when -- if we put that up, I think FDA is speaking to manufacturers of drug products and also drug</p>	<p>Page 82</p> <p>1 MR. STANOCH: Enough, Counsel. 2 THE WITNESS: I would say at this point in time, Mr. Stanoch, I can't add anything more to what I have already said. 5 But I'm not going to disagree with you that, you know, a drug-substance manufacturer that suspects a genotoxic impurity would want to follow the guidance and, you know, make sure that it's a selling point to customers that we're controlling genotoxic impurities. That's a good drug substance.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Uh-huh. Do you agree that nitrosamines are probable human carcinogens?</p> <p>14 MS. LOCKARD: Objection. Outside the scope of his retention, his expert report, his disclosure.</p> <p>17 THE WITNESS: Yeah, I'm certainly not offering opinion about that, but I have read the statements in the materials cited and some of the materials considered that would cause me to agree with what you said, Mr. Stanoch.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Do you agree that nitrosamines are genotoxic?</p> <p>25 A. Yeah, for purposes of discussions I will</p>
<p>1 substances.</p> <p>2 Q. Uh-huh. All right. I'm going to repeat my question a little bit ago because you didn't answer it when you said you wanted to look at the MCH guidance.</p> <p>6 So would you agree that under the ICH M7(R1) guidance from 2015, it would be incumbent on an API manufacturer that suspected a genotoxic impurity to attempt to characterize it, test it, potentially set limits for it, and to let the regulatory body and its API customers know?</p> <p>12 MS. LOCKARD: I am going to object to this question. He said he's not going to answer it. He wants to look at the document. So you are asking him to interpret a document and you are refusing to provide it to him, so I have an objection.</p> <p>17 We can take a break and get it if you want him to interpret it. It's also outside the scope of his expert opinion, however.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Go ahead, Dr. Williams.</p> <p>22 A. I'm sorry, Mr. Stanoch.</p> <p>23 Q. Please answer the question.</p> <p>24 MS. LOCKARD: If you can answer the question.</p>	<p>Page 83</p> <p>1 agree with that, Mr. Stanoch.</p> <p>2 Q. Do you agree that nitrosamines are not an active ingredient in any FDA-approved drug?</p> <p>4 MS. LOCKARD: Objection. Speculation.</p> <p>5 THE WITNESS: To the best of my knowledge, Mr. Stanoch, I can agree with that.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Uh-huh. Do you agree that the presence of nitrosamines even at trace level is considered unacceptable because these impurities are probable human carcinogens?</p> <p>12 MS. LOCKARD: Objection. Outside the scope of his retention and his expert report on class certification. He is not here to testify about whether the drug is a potential human carcinogen. But if you want to waste your time asking him causation questions, have at it.</p> <p>18 MR. STANOCH: Counsel, I don't need the colloquy. Thank you.</p> <p>20 Please answer, Dr. Williams.</p> <p>21 THE WITNESS: Would you restate the question, Mr. Stanoch? I'm sorry.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Sure. Do you agree that the presence of nitrosamines even at trace level is considered</p>

<p>1 unacceptable because these impurities are probable 2 human carcinogens?</p> <p>3 MS. LOCKARD: Same objection. It's 4 outside of his scope, the class-certification expert 5 report. He is not here to give a causation opinion.</p> <p>6 THE WITNESS: But in answer to your 7 question, Mr. Stanoch, no, I don't agree with that.</p> <p>8 BY MR. STANOCHE:</p> <p>9 Q. Stand by. Stand by, sir.</p> <p>10 You are familiar with the U.S. 11 Pharmacopeia Association, right, the USP?</p> <p>12 A. Yes, Mr. Stanoch, I am.</p> <p>13 Q. Yeah, you mean you used to be affiliated 14 with them, right?</p> <p>15 A. I was an employee of USP between 2000 and 16 2014.</p> <p>17 Q. Right. I'm going to mark another exhibit. 18 (Whereupon, Exhibit 4 was marked for 19 identification.)</p> <p>20 BY MR. STANOCHE:</p> <p>21 Q. You are going to have to look on your 22 screen, unfortunately, Dr. Williams. I don't have a 23 copy of this in the binder available.</p> <p>24 Can you pull it up, or would you like me 25 to share my screen? Exhibit 4.</p>	<p>Page 86</p> <p>1 MR. HARKINS: The exhibit share is what 2 you are talking about.</p> <p>3 MS. LOCKARD: The exhibit-share box is 4 what I'm talking about.</p> <p>5 THE WITNESS: Oh.</p> <p>6 MR. HARKINS: Open the chat, Roger.</p> <p>7 THE WITNESS: Oh.</p> <p>8 (Whereupon, a brief discussion off the 9 record.)</p> <p>10 THE WITNESS: Okay. I'm opening the chat 11 room, and --</p> <p>12 MR. HARKINS: Hold on. Let me -- someone 13 repaste the link to the exhibit share, please?</p> <p>14 Sorry. Can someone please repaste the 15 link to the exhibit share?</p> <p>16 All right. Can you hear me in the room?</p> <p>17 MR. STANOCHE: We can hear you, Steve.</p> <p>18 THE VIDEOGRAPHER: I might be able to 19 retrieve it from the chat.</p> <p>20 MR. HARKINS: Oh. I think that's it.</p> <p>21 THE VIDEOGRAPHER: Okay. Yeah, you got 22 it.</p> <p>23 MR. HARKINS: You control it here on the 24 separate screen, and you can scroll it down from 25 there.</p>
<p>1 A. Oh, I'll rely on you to give me something 2 that I can look at.</p> <p>3 Q. Okay. Stand by, sir.</p> <p>4 I'm now sharing my screen. This is 5 Exhibit 4 in the public folder.</p> <p>6 Do you see this, sir?</p> <p>7 A. Could we open the box and get it out of 8 the box?</p> <p>9 MS. LOCKARD: Is it in the binder?</p> <p>10 MR. STANOCHE: It's not in the binder. I'm 11 sorry.</p> <p>12 THE WITNESS: I think you are showing 13 me -- it looks like a PowerPoint; is that correct?</p> <p>14 BY MR. STANOCHE:</p> <p>15 Q. Yeah, this is the -- correct. This is the 16 cover page of a webinar in which Naiffer Romero of 17 USP spoke on nitrosamine impurities?</p> <p>18 A. Yeah, I don't see it very clearly. Can 19 you expand it or --</p> <p>20 MS. LOCKARD: Can you get it up out of the 21 box?</p> <p>22 THE WITNESS: I don't --</p> <p>23 MR. STANOCHE: It's not in the box, 24 Counsel, I'm sorry.</p> <p>25 THE WITNESS: Not in the box.</p>	<p>Page 87</p> <p>1 THE WITNESS: Can I make it bigger?</p> <p>2 MR. HARKINS: You should be able to zoom, 3 yeah.</p> <p>4 THE WITNESS: Okay. I'm looking at it, 5 Mr. Stanoch.</p> <p>6 BY MR. STANOCHE:</p> <p>7 Q. Okay. Great.</p> <p>8 A. Please proceed.</p> <p>9 Q. Sure. And you see the title page of this 10 slide, it's a USP webinar presentation?</p> <p>11 A. I think I do see that, yes.</p> <p>12 Q. All right. And then there is -- I have an 13 excerpt here, I have Slide 8 from that webinar on 14 the next page, if you scroll down, sir. The slide 15 says, "Background."</p> <p>16 A. Okay. I'm looking at "Background."</p> <p>17 Q. Great. And you will see that it's -- and 18 the highlighting, by the way, is original in the 19 document. I didn't modify this.</p> <p>20 A. Okay.</p> <p>21 Q. Do you see on the right it says, "Although 22 nitrosamines are also present in some foods and 23 drinking-water supplies, their presence in 24 medicines, even at trace level is considered 25 unacceptable because these impurities are probable</p>

<p>1 human carcinogens." Did I read that right?</p> <p>2 A. Yes, I think you read it correctly. And</p> <p>3 can you tell me the date of this document?</p> <p>4 Q. It's 2020.</p> <p>5 A. Oh, I see. All right. Thank you.</p> <p>6 Q. Uh-huh. And do you agree with that</p> <p>7 statement from this USP presentation?</p> <p>8 MS. LOCKARD: Objection. Asked and</p> <p>9 answered.</p> <p>10 THE WITNESS: I would say what I rely on</p> <p>11 is FDA's guidance document, which it does say you</p> <p>12 can have nitrosamine impurities within acceptable</p> <p>13 limits.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Uh-huh.</p> <p>16 A. So I would not agree with this statement.</p> <p>17 Q. Okay. And you see there in the middle,</p> <p>18 there is a fake Post-it that says, "Purpose of ICH</p> <p>19 M7"; do you see that?</p> <p>20 A. Yes, I do see that.</p> <p>21 Q. It reads, "Provide a practical framework</p> <p>22 that is applicable to the identification</p> <p>23 categorization, qualification, and control of</p> <p>24 mutagenic impurities to limit potential carcinogenic</p> <p>25 risk." Did I read that right?</p>	<p>Page 90</p> <p>1 though, that a drug-substance or product</p> <p>2 manufacturer would follow ICH M7 guidance to</p> <p>3 identify, characterize, qualify, and control</p> <p>4 mutagenic impurities on its own, correct?</p> <p>5 A. It could do. I mean, I'm not a</p> <p>6 toxicologist, but my understanding is that there</p> <p>7 could be many mutagenic impurities beyond the</p> <p>8 nitrosamine impurities that we're considering in</p> <p>9 this matter.</p> <p>10 Q. Right. And it's the expectation that</p> <p>11 manufacturers on their own would work to identify,</p> <p>12 characterize, qualify, and control mutagenic</p> <p>13 impurities to limit potential carcinogenic risk,</p> <p>14 correct?</p> <p>15 MS. LOCKARD: Objection. Outside the</p> <p>16 scope of his class-certification opinions.</p> <p>17 THE WITNESS: Yes, and I'm certainly not</p> <p>18 debating with you the content of the M7 document,</p> <p>19 Mr. Stanoch. If you read statements from that, I</p> <p>20 would probably generally agree with your statements.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Right. And you agree that it's the</p> <p>23 expectation that manufacturers would follow the ICH</p> <p>24 M7 guidance themselves, correct?</p> <p>25 MS. LOCKARD: Objection. Asked and</p>
<p>1 A. Yes, I think you are reading it correctly.</p> <p>2 Q. And would you agree with that statement</p> <p>3 about the purpose of ICH M7?</p> <p>4 A. Yes, that seems like a general statement,</p> <p>5 and I agree with it.</p> <p>6 Q. Right. And that would have been the case</p> <p>7 with ICH M7 guidance prior to the FDA's first take</p> <p>8 at establishing interim limits for nitrosamines in</p> <p>9 December 2018, correct?</p> <p>10 A. And although I didn't offer this as an</p> <p>11 opinion, I think FDA itself tended to follow the ICH</p> <p>12 M7 document, particularly with regard to the word</p> <p>13 "control." So when FDA is saying control, they are</p> <p>14 saying, we can put a limit on the NDMA impurity.</p> <p>15 Q. Well, the guidance is to the industry to</p> <p>16 deal with impurities when they find them in their</p> <p>17 drug substance or their drug products, right?</p> <p>18 A. Now, are you asking about M7?</p> <p>19 Q. Yes.</p> <p>20 A. Yes. And it's a general statement, but I</p> <p>21 think a specific example is the nitrosamine</p> <p>22 impurities, and that's what I alluded to in my</p> <p>23 report.</p> <p>24 Q. Right. Well, you mention control in the</p> <p>25 context of the FDA setting limits. The point is,</p>	<p>Page 91</p> <p>1 answered. Outside the scope.</p> <p>2 THE WITNESS: With the exception of</p> <p>3 nitrosamine, where, if I may say so, FDA did the</p> <p>4 work of M7 on behalf of the entire industry.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Well, prior to December 2018 there were no</p> <p>7 FDA interim limits, right?</p> <p>8 A. That's true.</p> <p>9 Q. Okay. But we had ICH M7 guidance,</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And the guidance set forth that</p> <p>13 manufacturers should identify, characterize,</p> <p>14 qualify, and control mutagenic impurities to limit</p> <p>15 potential carcinogenic risk, yes?</p> <p>16 A. I'm not debating the words of the</p> <p>17 guidance, if that's your question. I agree with the</p> <p>18 words of the guidance.</p> <p>19 Q. Well, I'm asking you about the application</p> <p>20 of the guidance, Dr. Williams, that even in the</p> <p>21 absence of the FDA interim limits in December 2018,</p> <p>22 was the expectation that a manufacturer would still</p> <p>23 attempt to identify, characterize, qualify, and</p> <p>24 control mutagenic impurities to limit potential</p> <p>25 carcinogenic risk?</p>

<p>1 MS. LOCKARD: Objection. Vague. Outside 2 the scope.</p> <p>3 THE WITNESS: Yeah, I didn't really 4 comment on this, Mr. Stanoch. Do you want me to 5 speculate?</p> <p>6 BY MR. STANOCHE:</p> <p>7 Q. I would like you to answer the question, 8 Dr. Williams.</p> <p>9 A. You know, the way I would say it, and I 10 think I have already alluded to this previously, is, 11 you know, an ANDA applicant generally follows the 12 guidances I cited in my report.</p> <p>13 And to the extent that they -- you know, 14 when they get into qualifying an impurity, they may 15 have to consider mutagenic or DNA-reactive 16 impurities, and then they would turn to the M7 17 guidance. But that is certainly a case-by-case 18 decision, and you would have to suspect the impurity 19 was present and you would have to be able to measure 20 it. So you are asking a very general question.</p> <p>21 Q. And the ICH M7 guidance is not confined to 22 ANDA applications, correct?</p> <p>23 A. That's my understanding. Again, if you 24 are going to ask me questions about it, it would 25 probably be best if I could see it.</p>	<p>1 the lines of your questioning.</p> <p>2 Q. So you can't tell me one way or the other 3 about whether the ICH M7 guidance applies throughout 4 the life of a drug?</p> <p>5 MS. LOCKARD: Objection. Asked and 6 answered.</p> <p>7 He said if you are going to ask him 8 questions about the application and interpretation 9 of the guidance, he wants to have it in front of 10 him, which is a fair request.</p> <p>11 BY MR. STANOCHE:</p> <p>12 Q. You can answer the question, Dr. Williams.</p> <p>13 MS. LOCKARD: Objection. It's 14 argumentative.</p> <p>15 THE WITNESS: I prefer not to answer the 16 question without seeing the guidance.</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. And which guidance do you want to see, 19 Doctor?</p> <p>20 A. M7.</p> <p>21 Q. What version?</p> <p>22 A. The current version.</p> <p>23 Q. What year?</p> <p>24 A. I think it's 2015.</p> <p>25 Q. Show me where it is in your reliance</p>
<p>1 Q. Well, we will get to specific parts of it, 2 but -- your understanding that the ICH M7 guidance 3 applies to the life of a drug from application 4 through commercialization, correct?</p> <p>5 A. Again, you know, I feel very uncomfortable 6 answering questions about a document that I haven't 7 seen and that I cite in my report, but I would say 8 it was not particularly important to my opinions.</p> <p>9 But again, you know, I'll be glad to walk 10 through it with you, Mr. Stanoch. I don't think it 11 is particularly appropriate for my opinions or 12 important to my opinions, but again, I'm certainly 13 here to be responsive to your questions.</p> <p>14 Q. Right. And you agree that the ICH M7 15 guidance applies throughout the life of a drug, 16 correct?</p> <p>17 A. I don't believe I said that. I think what 18 I said is if we're going -- if you are going to ask 19 me that question, I feel like I need to see the 20 guidance.</p> <p>21 Q. You can't tell me anything about the ICH 22 M7 guidance general applicability without looking at 23 it?</p> <p>24 A. I think, yes, I'm saying that. I would be 25 hesitant to make statements about the guidance along</p>	<p>1 Page 95</p> <p>1 materials and report, which version you want.</p> <p>2 MS. LOCKARD: Let me just put an objection 3 on the record. You are asking him questions about a 4 guidance that you haven't identified. He is asking 5 to see the guidance that you were questioning him 6 about. If you want to question him about a 7 document, identify it. Now you are telling him 8 to --</p> <p>9 MR. STANOCHE: Counsel, enough. Enough, 10 Counsel. Counsel, enough.</p> <p>11 (Overlapping speakers.)</p> <p>12 MR. STANOCHE: I'm asking him to tell me 13 the document he wants. I'm asking him to tell me 14 what document he wants. I'm trying to comply with 15 his request, Counsel. Please, let him tell me what 16 he wants to see. Thank you.</p> <p>17 We have lost Dr. Williams. Dr. Williams, 18 we can't see you.</p> <p>19 MS. LOCKARD: We're on break. We can go 20 off the record. You can keep running.</p> <p>21 MR. STANOCHE: Wait a minute. Wait a 22 minute. Wait a minute. Wait a minute. I am not 23 agreeing to go off the record. I have a pending 24 question to the witness to tell me what document he 25 said he needs to see. I am not agreeing to go off</p> <p>1 Page 96</p>

<p>1 the record.</p> <p>2 Q. Are you going to answer the question,</p> <p>3 Dr. Williams?</p> <p>4 MR. STANOCH: Or, Counsel, are you going</p> <p>5 to instruct him not to answer it?</p> <p>6 Well, let it be noted that despite the</p> <p>7 nonagreement and the pending question, both the</p> <p>8 witness and counsel have gone off.</p> <p>9 Let's keep running.</p> <p>10 THE WITNESS: I have been instructed by</p> <p>11 counsel to come back, Mr. Stanoch, and now I'm</p> <p>12 trying to look for the guidance that you are</p> <p>13 alluding to.</p> <p>14 MR. STANOCH: Thank you.</p> <p>15 THE WITNESS: And I would say we can look,</p> <p>16 if you agree, to the guidance for industry</p> <p>17 genotoxic -- the other one -- I would really</p> <p>18 appreciate it if you would pick the guidance because</p> <p>19 you are talking about it. But yes, here it is.</p> <p>20 I have been handed it in a copy. M7,</p> <p>21 Revision 1, Addendum to ICH M7. Now, that makes me</p> <p>22 a little nervous because it's an addendum, and it</p> <p>23 makes me wonder, where is the M7(R1)? But if we can</p> <p>24 look at M7(R1), I'll be glad to answer questions</p> <p>25 about it if I can.</p>	<p>Page 98</p> <p>1 benefit of all of your colleagues on Zoom. Well,</p> <p>2 that's going to take me time.</p> <p>3 Q. Doctor, I can pull up the March 2018</p> <p>4 guidance. You want to work with that for now? Or</p> <p>5 would --</p> <p>6 A. And I also think it would be important to</p> <p>7 go to my report where I reference this document.</p> <p>8 Let me see if I can find that.</p> <p>9 MS. LOCKARD: And while he is doing that,</p> <p>10 Exhibit 4 was the USP PowerPoint. It looks like</p> <p>11 there are only two pages of that. Do you have</p> <p>12 the -- are you making the full PowerPoint the</p> <p>13 exhibit?</p> <p>14 MR. STANOCH: Those are excerpts from the</p> <p>15 webinar. We will mark the entire webinar.</p> <p>16 Q. Well, Doctor, let's see if we can cut</p> <p>17 through this a little bit, shall we? You agree, do</p> <p>18 you not, that ICH M7 guidance has been in effect --</p> <p>19 has been effective in different forms for quite some</p> <p>20 time, yes?</p> <p>21 A. I can agree with that, Mr. Stanoch,</p> <p>22 please, if the --</p> <p>23 Q. Sure. Sure. And why don't we get a</p> <p>24 ballpark. I mean, can we say that at least since</p> <p>25 2003 there has been some form of ICH M7 guidance?</p>
<p>1 BY MR. STANOCH:</p> <p>2 Q. I'm --</p> <p>3 A. Can you proceed, Mr. Stanoch?</p> <p>4 Q. Well, I want to make sure we have the</p> <p>5 right documents in front of us, and I have to mark</p> <p>6 it, Dr. Williams. So why don't you tell me the date</p> <p>7 of the document you are looking at?</p> <p>8 A. Well, what I have been handed is M7(R1),</p> <p>9 dated March 31st, 2017, and then a M7(R1) addendum,</p> <p>10 so it's lot of paper and I'm looking at two</p> <p>11 documents.</p> <p>12 MS. LOCKARD: And for the record, I still</p> <p>13 don't know what it is that your question is asking</p> <p>14 about, so we are trying to print whatever we think</p> <p>15 you are asking about, but you have refused so far to</p> <p>16 identify -- counsel has refused to identify the</p> <p>17 specific guidance that he is asking the doctor to</p> <p>18 interpret, so --</p> <p>19 THE WITNESS: Okay. I'm prepared to</p> <p>20 answer questions. Did you get the dates of the</p> <p>21 documents I'm looking at? The M7, Revision 1, is</p> <p>22 March 2017.</p> <p>23 MS. LOCKARD: Can you hear us?</p> <p>24 MR. STANOCH: Yeah, I'm trying to pull up</p> <p>25 the version that you have in the hard copy for the</p>	<p>Page 99</p> <p>Page 101</p> <p>1 A. You know, I'd hesitate from that, but for</p> <p>2 purpose of a discussion let me agree so that we can</p> <p>3 go forward.</p> <p>4 Q. I appreciate that. I won't hold you to</p> <p>5 the particular date. I was just trying to pick a</p> <p>6 date that we could just move forward from. So --</p> <p>7 and we can agree, can we not, that there has been</p> <p>8 revisions and addenda to the M7 guidance over time,</p> <p>9 correct?</p> <p>10 A. Okay. Let me agree.</p> <p>11 Q. And would you agree that even in the</p> <p>12 absence of FDA interim limits for nitrosamines,</p> <p>13 there was an expectation that a manufacturer would</p> <p>14 adhere to the ICH M7 guidance concerning genotoxic</p> <p>15 impurities, whatever the status of that guidance was</p> <p>16 at the particular time?</p> <p>17 MS. LOCKARD: Objection. These are</p> <p>18 liability opinions and outside the scope of his</p> <p>19 report.</p> <p>20 THE WITNESS: Yeah, I am very hesitant</p> <p>21 with your general statements, but again, I won't</p> <p>22 contest them so we can move forward. Go ahead,</p> <p>23 Mr. Stanoch.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. I'm a little unclear what you mean by</p>

<p>Page 102</p> <p>1 don't contest them. Does that mean you will agree 2 with that question?</p> <p>3 MS. LOCKARD: Objection. Vague.</p> <p>4 THE WITNESS: You know, it would be 5 much -- can you restate the question?</p> <p>6 BY MR. STANOCH:</p> <p>7 Q. Sure. Would you agree that even in the 8 absence of FDA interim limits for nitrosamines, 9 there was an expectation that a manufacturer would 10 adhere to the ICH M7 guidance concerning genotoxic 11 impurities as that guidance stood at the particular 12 time?</p> <p>13 MS. LOCKARD: Objection. Vague. Outside 14 the scope of his expert report.</p> <p>15 THE WITNESS: Yes, it's not any opinion I 16 offered, but I won't debate what you are saying, so 17 I can agree with it, Mr. Stanoch.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Fair enough. And do you agree that the 20 ICH M7 guidance includes nitrosamines in the cohort 21 of concern? And if you need to look at the version 22 in front of you, that's fine, and we could mark it 23 later.</p> <p>24 A. I don't know where I see nitrosamines 25 here, and I didn't look for it.</p>	<p>Page 104</p> <p>1 reading anything correctly.</p> <p>2 THE WITNESS: No, okay.</p> <p>3 All right. Well, I'm a little hesitant 4 about answering, Mr. Stanoch.</p> <p>5 MR. STANOCH: Then stand by for an 6 exhibit, sir.</p> <p>7 I'm going to mark the next exhibit, sir.</p> <p>8 (Whereupon, Exhibit 5 was marked for 9 identification.)</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Exhibit 5. This is actually Tab 2 in your 12 binder. You can take the binder out of the box we 13 sent you as a courtesy.</p> <p>14 MS. LOCKARD: Hold on. We are opening the 15 box. There is one black binder in here. Tab 2?</p> <p>16 MR. STANOCH: Yes, please.</p> <p>17 MS. LOCKARD: Okay.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Tell me when you have that, Doctor.</p> <p>20 A. I think I'm looking at it. Tab 2, it is a 21 letter from FDA to -- I don't see who it's to. But 22 it looks to be about a five-page letter.</p> <p>23 Q. Right. It's a general advice letter from 24 the FDA. You see that in the upper right, "General 25 Advice"?</p>
<p>Page 103</p> <p>1 Q. All right. Let --</p> <p>2 A. Can you point it out where you see it, 3 Mr. Stanoch?</p> <p>4 Q. Sure. Put that aside, then. Let's put it 5 a different way. Are you aware that the FDA has 6 stated that N-nitroso compounds are identified as a 7 cohort of concern in ICH M7 guidance?</p> <p>8 MS. LOCKARD: Objection. Outside the 9 scope of his expert report.</p> <p>10 THE WITNESS: Yeah, I see no reason to 11 deny what you are saying, so I'll agree with it to 12 continue the discussion, Mr. Stanoch.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Thank you. I appreciate that, Doctor.</p> <p>15 And a substance that falls within the ICH 16 cohort of concern should be controlled, correct?</p> <p>17 MS. LOCKARD: Objection. Falls outside of 18 the scope of his class-certification opinions.</p> <p>19 THE WITNESS: You know, I could probably 20 agree more readily if you could show me where you 21 are reading in the guidance. But again, for 22 purposes of the discussion, I won't debate what you 23 are saying, Mr. Stanoch. I'm sure you are reading 24 it correctly.</p> <p>25 MS. LOCKARD: I wouldn't assume that he is</p>	<p>Page 105</p> <p>1 A. I do see that.</p> <p>2 Q. Uh-huh. And do you see --</p> <p>3 MS. LOCKARD: There is no Bates number, 4 for those on the call.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Would you look at the last paragraph of 7 the first page, sir?</p> <p>8 A. Last paragraph, first page.</p> <p>9 Q. It begins, "Nitrosamine compounds." Do 10 you see that?</p> <p>11 A. Wait a minute. Oh, "Nitrosamine 12 compounds." Yes, I'm with you, Mr. Stanoch. Go 13 ahead.</p> <p>14 Q. Wonderful. Why don't you read for us the 15 first few sentences of that paragraph?</p> <p>16 A. "Nitrosamine compounds are potent 17 genotoxic carcinogens in several nonclinical species 18 and are classified as probable human carcinogens by 19 the International Agency for Research on Cancer. In 20 fact, 'N-nitroso' compounds are identified as a 21 'cohort of concern' in internationally" recognized 22 "guidance, ICH M7," and then it states the name. 23 Should I stop there?</p> <p>24 Q. Keep going. Slowly, please, for the court 25 reporter.</p>

<p style="text-align: right;">Page 106</p> <p>1 A. "ICH M7 recommends that known mutagenic 2 carcinogens, such as nitrosamines," to "be 3 controlled at or below the acceptable cancer risk 4 level. Due to their known potent carcinogenic 5 effects, and because it is feasible to limit these 6 impurities by taking reasonable steps to prevent or 7 eliminate their presence, FDA has determined that 8 there is no acceptable specification for 9 nitrosamines in ARB API and DP."</p> <p>10 Q. That's fine. Okay. And, oh, actually, 11 why don't you read the one more sentence?</p> <p>12 A. "Therefore, FDA advises that nitrosamines 13 should be absent (not detectable as described below) 14 from ARB API and ARB drug products."</p> <p>15 Q. Okay. Thank you.</p> <p>16 So, first of all, were you aware of this 17 general advice letter from the FDA prior to right 18 now?</p> <p>19 A. No.</p> <p>20 Q. Okay. Second of all, do you agree with 21 the FDA's statement in this letter that nitrosamine 22 compounds are potent genotoxic carcinogens?</p> <p>23 MS. LOCKARD: Objection. Outside the 24 scope of his class-certification opinions. He is 25 not here to give a causation opinion.</p>	<p style="text-align: right;">Page 108</p> <p>1 And the next sentence, do you agree with 2 the FDA that N-nitroso compounds are part of the 3 cohort of concern under ICH M7 guidance?</p> <p>4 A. Yes, I see the words, and I think you are 5 reading them correctly.</p> <p>6 Q. And do you agree with that statement, 7 regardless of whether I read it correctly?</p> <p>8 MS. LOCKARD: Does he agree that it -- 9 right. Objection. Vague.</p> <p>10 THE WITNESS: I see no reason to disagree 11 with the words in this letter.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Perfect. And do you agree, then, that as 14 part of the cohort of concern, nitrosamines should 15 be controlled?</p> <p>16 A. Yes, I can agree with that.</p> <p>17 Q. All right. And do you agree generally 18 that nitrosamines can be controlled?</p> <p>19 A. Yes, I think FDA documented that in its 20 December 2018 statement.</p> <p>21 Q. And do you agree that nitrosamines can be 22 avoided entirely?</p> <p>23 A. You know, that's sort of a case-by-case 24 question.</p> <p>25 But what is perplexing me about this</p>
<p style="text-align: right;">Page 107</p> <p>1 THE WITNESS: And I know I'm not supposed 2 to ask questions, but I don't see a date on this 3 letter. Is there a date?</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. It doesn't appear that it has a date on 6 it.</p> <p>7 A. And also, if I may say so, I think this 8 conflicts with the FDA guidance on nitrosamine 9 impurities, but we can have that conversation if you 10 wish.</p> <p>11 But anyway, back to you, Mr. Stanoch. Am 12 I answering your questions about this document?</p> <p>13 Q. Well, not yet. The question was: Do you 14 agree with the FDA's statement that nitrosamine 15 compounds are potent genotoxic carcinogens?</p> <p>16 MS. LOCKARD: Objection. Outside the 17 scope of his class-certification opinions. He is 18 not here to give a causation opinion.</p> <p>19 THE WITNESS: Yes, and I'm not going to 20 debate the wording in this letter. It seems like a 21 formal letter from the agency, and I'm not in a 22 position to disagree with FDA on this point.</p> <p>23 So please continue, Mr. Stanoch.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. I certainly will. Thank you, Doctor.</p>	<p style="text-align: right;">Page 109</p> <p>1 letter is I think the FDA guidance says you can have 2 nitrosamine impurities as long as they stay within 3 the acceptable intake limits.</p> <p>4 Q. Uh-huh.</p> <p>5 A. So I see a dissonance between this letter 6 and the FDA guidance.</p> <p>7 Q. Uh-huh.</p> <p>8 A. But please continue.</p> <p>9 Q. And you say "a case-by-case basis." Do 10 you mean by that that it would be on a particular 11 manufacturer to assess whether nitrosamines could be 12 avoided entirely in its manufacturing process?</p> <p>13 A. Yes, I agree with the way you stated that.</p> <p>14 Thank you.</p> <p>15 Q. Uh-huh. Yep. And were you aware prior to 16 seeing this letter that at one point the FDA said 17 that it had determined that there is no acceptable 18 specification for nitrosamines in ARB API and DP?</p> <p>19 A. Well, as I say, I think that's not what 20 the guidance says, but I see where it says it here 21 in this letter.</p> <p>22 Q. Uh-huh. You keep saying "guidance."</p> <p>23 Which guidance do you mean specifically?</p> <p>24 A. It was the nitrosamine impurities guidance 25 that I cite in my report. It came out in September</p>

<p>1 of 2020, and then it was updated in February of 2 2021.</p> <p>3 Q. Uh-huh. So at the time this FDA general 4 advice letter was put out, it was the FDA's view 5 that there is no acceptable specification for 6 nitrosamines in ARB API and DP, correct?</p> <p>7 A. Yes, and we don't quite know when because 8 we can't see a date on this letter.</p> <p>9 Q. Well, I believe the letter was from 10 sometime in 2019.</p> <p>11 MS. LOCKARD: Objection to counsel 12 testifying.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Assume the letter was from 2019, Doctor, 15 okay?</p> <p>16 A. Okay. I'm willing to make that 17 assumption. It may have come out, then --</p> <p>18 Q. Great.</p> <p>19 A. It may have come out, then, before the 20 first iteration of the draft September 2020 21 guidance, and therefore the guidance superseded this 22 document.</p> <p>23 Q. Sure. Then --</p> <p>24 A. That would resolve my dissonance.</p> <p>25 Q. And that may be the sequence of events,</p>	<p>Page 110</p> <p>1 MS. LOCKARD: What paragraph are you 2 looking at?</p> <p>3 MR. STANOCH: Same one.</p> <p>4 THE WITNESS: Uh-huh. Well, we can keep 5 on looking at this letter. Is there a question 6 pending, Mr. Stanoch?</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. There was. The FDA goes on to say they 9 used the interim limits only to guide immediate 10 decision-making for the product recalls. Do you see 11 that?</p> <p>12 A. I do see that.</p> <p>13 Q. Uh-huh. And were you aware of that prior 14 to today?</p> <p>15 MS. LOCKARD: Objection. Vague.</p> <p>16 THE WITNESS: And this is the first time I 17 have seen this letter.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Okay. Let's put that aside for now, 20 Doctor.</p> <p>21 A. Okay. Thank you.</p> <p>22 Q. Why don't you flip to Tab 3 in your 23 binder. It will be introduced as Exhibit 6.</p> <p>24 (Whereupon, Exhibit 6 was marked for 25 identification.)</p>
<p>Page 111</p> <p>1 Doctor. But at the time this letter came out, 2 right, the FDA had determined there is no acceptable 3 specification for nitrosamines in ARB API and DP, 4 right?</p> <p>5 A. I see the wording in the letter. I don't 6 disagree with the way you are stating the wording. 7 And I'm willing to make the assumption it came out 8 sometime in 2019.</p> <p>9 Q. So then, at the time of this letter, there 10 should be no nitrosamines in any valsartan API or 11 drug product, correct?</p> <p>12 MS. LOCKARD: Objection. Vague.</p> <p>13 Foundation.</p> <p>14 THE WITNESS: Well, I think FDA is even 15 saying in this letter that they provided interim 16 acceptable limits for nitrosamine impurities in 17 ARBs. So I don't know how to kind of piece together 18 what it's saying here versus, well, the other 19 realities of their December 2018 decision and the 20 guidance that I cited in my report.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Uh-huh. The FDA goes on to say that they 23 used the interim limits only to guide immediate 24 decision-making for the product recalls. Do you see 25 that?</p>	<p>Page 113</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Tell me when you are there, Doctor.</p> <p>3 A. I'm there. I see it. M7(R1). Is that 4 what we're talking about, March 2018?</p> <p>5 Q. Yes, sir. We're on the same document.</p> <p>6 That's a good step. So are you familiar with this 7 document?</p> <p>8 A. I'm aware of it. I did not study it 9 closely for my report.</p> <p>10 Q. That's okay. But you understand that it's 11 the ICH guidance as of March 2018, correct?</p> <p>12 A. Yes, I do. And then the one I had printed 13 out for me before was dated 31 March 2017.</p> <p>14 Q. Right. And I don't have a copy of exactly 15 what you were handed. We can get it.</p> <p>16 But this goes back to our point that the 17 guidance might have went through various iterations 18 over time generally, right?</p> <p>19 A. Yes, exactly. That's how the ICH 20 guidances work. So I'm prepared to consider this 21 with you, Mr. Stanoch.</p> <p>22 Q. That's great. So why don't we turn to 23 page 5 of this document, sir?</p> <p>24 A. All right.</p> <p>25 Q. And tell me when you are there.</p>

<p>1 A. I'm there. Where it says, "General 2 Principles"?</p> <p>3 Q. Yes, sir. And then you see the paragraph 4 in the middle, "A Threshold of Toxicological 5 Concern"?</p> <p>6 A. I do see that.</p> <p>7 Q. Uh-huh. And do you see at the end that 8 this March 2018 guidance states, "This group of high 9 potency mutagenic carcinogens, referred to as the 10 cohort of concern, comprises aflatoxin-like-, 11 N-nitroso-, and alkyl-azoxy compounds," correct?</p> <p>12 A. Yes, I do see that.</p> <p>13 Q. All right. And N-nitroso compounds, those 14 would include the NDMA and NDEA nitrosamines that 15 you discuss in your report, correct?</p> <p>16 A. I think you are saying that correctly.</p> <p>17 Thank you, Mr. Stanoch.</p> <p>18 Q. And then what is your understanding of 19 cohort of concern, sir?</p> <p>20 A. As the words say here, it's a group of 21 high-potency mutagenic carcinogens that comprises 22 the three -- excuse me, Mr. Stanoch -- that 23 comprises the three types of compounds stated in the 24 sentence. A cohort of concern, apparently they are 25 trying to classify some particularly mutagenic</p>	<p>Page 114</p> <p>1 beginning of the paragraph, it says, "was developed 2 to define an acceptable intake for any unstudied 3 chemical that poses a negligible risk." So I guess 4 if it is below the threshold, the risk is 5 negligible, but if it is above, you begin to have 6 some concern. Please correct me if --</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Right. I apologize. Are you done, 9 Doctor?</p> <p>10 A. Yes, I think I am. Thank you, 11 Mr. Stanoch.</p> <p>12 Q. Yes. And just following along, you see 13 later in that paragraph it says, "For application of 14 a TTC in the assessment of acceptable limits of 15 mutagenic impurities," and the sentence continues. 16 Do you see that?</p> <p>17 A. I do.</p> <p>18 Q. Right. And the purpose of the TTC was to 19 assess acceptable limits of impurities in drug 20 substances, correct?</p> <p>21 MS. LOCKARD: Objection. Outside the 22 scope of his expert opinion. You are asking him 23 what the purpose of the TTC was. This is not part 24 of his class-certification report.</p> <p>25 THE WITNESS: Yeah, and -- the only thing</p>
<p>Page 115</p> <p>1 carcinogens, as stated here in the sentence.</p> <p>2 Q. And the purpose of that is to alert 3 industry that limits for the cohort of concern might 4 be much lower than the threshold of toxicological 5 concern that might otherwise be defined per the 6 guidance, right?</p> <p>7 MS. LOCKARD: Objection. Vague. And 8 outside the scope of his testimony.</p> <p>9 THE WITNESS: Yeah. And you are beginning 10 to ask me questions that I would call 11 pharmacology/toxicology questions.</p> <p>12 I can read the sentences here and agree 13 with them, Mr. Stanoch. For example, it says, "Some 14 structural groups were identified to be of such high 15 potency," and then the sentence continues. And 16 these high potency are referred to as a cohort of 17 concern, and then it lists the three compounds that 18 fall into the structural categories that we have 19 already discussed.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Uh-huh. And then the threshold of 22 toxicological concern, what does that relate to?</p> <p>23 MS. LOCKARD: Objection. Vague. Outside 24 the scope.</p> <p>25 THE WITNESS: Well, if we go back to the</p>	<p>Page 117</p> <p>1 I can do is read the words and sort of say I have a 2 general understanding of what they are saying. I'm 3 certainly not a pharmacologist-toxicologist.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. I'm not asking for a pharmacology or 6 toxicology opinion, Doctor. I'm asking your 7 understanding in the context of a report where you 8 talk about thresholds of limits that may or may not 9 have existed.</p> <p>10 We're looking now here at the ICH 11 guidance, the March 20th, 2018, version, and it's 12 talking about acceptable limits of mutagenic 13 impurities, right?</p> <p>14 A. But I still don't see limits. Am I 15 missing limits?</p> <p>16 Q. Well, the whole thrust is talking about 17 assessment of acceptable limits, is it not?</p> <p>18 A. I think it's talking about it generally, 19 but when I spoke about it in my report, I was 20 talking specifically about the limits that FDA 21 created in December 2018 and nothing more.</p> <p>22 Q. Right. And what I'm getting at, Doctor, 23 is: Prior to the FDA's interim limits, there 24 already was industry guidance on acceptable limits 25 of mutagenic impurities, correct?</p>

<p>1 MS. LOCKARD: Objection. Outside the 2 scope of his opinions.</p> <p>3 THE WITNESS: If you are talking about 4 this document, I would certainly agree with you.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Great. And you would agree for any other 7 iteration of this M7(R1) guidance prior to this one 8 that spoke of acceptable limits of mutagenic 9 impurities as well, correct?</p> <p>10 A. Well, that's a broad statement, but again, 11 let me agree for purposes of discussion.</p> <p>12 Q. I appreciate that. And then let's flip to 13 page 14. Let me know when you are there, sir.</p> <p>14 A. Okay. I'm there.</p> <p>15 Q. And do you see Section E, sir?</p> <p>16 A. I do.</p> <p>17 Q. Right. And do you see there is three 18 bullets under Section E?</p> <p>19 A. I do.</p> <p>20 Q. And the third bullet is talking about the 21 cohort of concern impurities again, fair?</p> <p>22 A. I see that, yes.</p> <p>23 Q. And it notes, "If these compounds are 24 found as impurities in pharmaceuticals, acceptable 25 intakes for these high-potency carcinogens would</p>	<p>1 what we're talking about, what are the acceptable 2 intake limits. And I think FDA has -- they provided 3 those in December 2018. That's what I stated in my 4 report.</p> <p>5 Q. You --</p> <p>6 A. You know, as long as we're sort of looking 7 at this ad hoc document that I did not study or cite 8 in my report other than to notice its availability, 9 Mr. Stanoch, I might draw your attention to the 10 first bullet on this page, where it says, "Higher 11 acceptable intakes may be justified when human 12 exposure to the impurity will be much greater from 13 other sources, e.g., food." Now, of course that's 14 exactly the case with nitrosamines.</p> <p>15 Q. Well, thank you for the gratuitous 16 statement, Doctor, but let's talk about that.</p> <p>17 All three of these bullets we are looking 18 at, flexibilities in approaches, they are suggesting 19 to manufacturers to conduct a case-by-case approach 20 to come up with acceptable intake limits for 21 products, correct?</p> <p>22 A. Yes, and in the case of nitrosamines, in 23 the current matter, FDA did that for manufacturers, 24 as the prior letter you showed me noticed, in 25 December 2018.</p>
<p>1 likely be significantly lower than the acceptable 2 intakes defined in this guidance."</p> <p>3 Did I read that right?</p> <p>4 A. I can agree with your reading of the 5 words.</p> <p>6 Q. Uh-huh. Right. And then you see it 7 further says, "Although the principles of this 8 guidance can be used, a case-by-case approach 9 using," for example, "carcinogenicity data from 10 closely related structures, if available, should 11 usually be developed to justify acceptable intakes 12 for pharmaceutical development and marketed 13 products."</p> <p>14 Did I read that correctly?</p> <p>15 A. I think you are reading it correctly, yes, 16 no question about that.</p> <p>17 Q. I appreciate that, Doctor.</p> <p>18 And so what the guidance we're looking at 19 here is saying is that for the cohort of concern 20 impurities, which includes the nitrosamine 21 compounds, at least as of the date of this guidance 22 of March 2018, that acceptable intake limits for it 23 should be developed for both the development and 24 marketing of pharmaceutical products?</p> <p>25 A. Well, I agree with you. I think that's</p>	<p>1 Q. Right. Well, prior to the FDA's interim 2 limits for nitrosamines in December of 2018, there 3 already was industry guidance, was there not, that 4 manufacturers should be conducting their own 5 assessments to potentially set limits for impurities 6 such as nitrosamines?</p> <p>7 MS. LOCKARD: Objection. Outside the 8 scope of his class-certification opinions.</p> <p>9 THE WITNESS: Yes, and remember, we're 10 dealing with a situation where FDA said this was 11 unexpected, they didn't know how it occurred. They 12 had many other caveats that indicated, if you will, 13 their surprise that came about in the summer of 14 2018. These are very low-level impurities, and you 15 would have to suspect them and then have analytical 16 capability to identify them, notwithstanding all the 17 words in this guidance.</p> <p>18 So I'm glad to walk through the guidance 19 with you. I think it's an interesting and important 20 guidance, Mr. Stanoch, but it really only is 21 tangentially related to my report.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. So it's not important to your opinions 24 that there already was industry guidance on how to 25 address levels of nitrosamines in drugs prior to the</p>

<p style="text-align: right;">Page 122</p> <p>1 December 2018 FDA interim guidance?</p> <p>2 MS. LOCKARD: Objection. Outside of the 3 scope of his opinions. That's not what he was 4 retained, that's not what he discussed in his expert 5 report.</p> <p>6 THE WITNESS: Yeah, I'm listening to the 7 two counsel, and I think the way you both said it is 8 correct. I was considering other factors and 9 information that I cited in my report that led to my 10 opinions, and I certainly haven't changed my 11 opinions as a result of the review of this document.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Okay. Are you aware of any Novartis 14 Diovan product sold in the -- 15 (Reporter clarification.)</p> <p>16 MR. STANOCH: No problem. Let's start 17 over.</p> <p>18 Q. Are you aware of any Novartis Diovan 19 product sold in the United States that contained 20 NDMA?</p> <p>21 A. I am not.</p> <p>22 Q. Are you aware of any Novartis Diovan 23 product sold in the United States that contained 24 NDEA?</p> <p>25 A. No, I am not.</p>	<p>1 to June 20, 2018, but Teva could not?</p> <p>2 MS. LOCKARD: Objection. Outside the 3 scope of his expert opinion on class-certification 4 issues. Vague. Lacks foundation. Argumentative.</p> <p>5 THE WITNESS: Again, Mr. Stanoch, I just 6 have not seen any documents to that point. If you 7 can point to them in my materials considered, I 8 would be glad to look at them with you.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Uh-huh. Well, you tell me, Doctor, did 11 you look at any materials that identify how Novartis 12 was able to discover NDMA in ZHP's valsartan API?</p> <p>13 MS. LOCKARD: Objection. Outside the 14 scope of his class-certification opinions. Lacks 15 foundation. Speculation.</p> <p>16 THE WITNESS: And my apologies, 17 Mr. Stanoch. I thought I had answered that 18 question. I have not seen any documents, anywhere, 19 that speak to Novartis' testing of any products for 20 nitrosamines.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Can you tell me what methods Novartis used 23 to detect NDMA in ZHP's valsartan API?</p> <p>24 MS. LOCKARD: Objection. Outside the 25 scope of his class-certification opinions. Lacks</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. You are aware, are you not, that Novartis 2 detected NDMA in ZHP's valsartan API prior to 3 June 20th, 2018, correct?</p> <p>4 A. You know, I have heard statements to that 5 effect from counsel, but I don't think I have ever 6 seen any documents for it. I don't think a document 7 exists on my materials-considered list, and I 8 certainly didn't cite anything like that in my 9 report.</p> <p>10 Q. Uh-huh. Can you tell us how -- 11 A. But I would be glad to look at such a 12 document if you have it, Mr. Stanoch.</p> <p>13 Q. Uh-huh. Can you tell us how Novartis was 14 able to identify NDMA in ZHP's valsartan API prior 15 to June 20, 2018?</p> <p>16 MS. LOCKARD: Objection. Outside the 17 scope of his expert opinions on class certification. 18 Lacks foundation. Speculation.</p> <p>19 THE WITNESS: You know, I'm not, 20 Mr. Stanoch. I just don't have any documents to 21 speak to that. I would be glad to look at them if 22 you have them.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Uh-huh. Can you tell us how Novartis was 25 able to identify NDMA in ZHP's valsartan API prior</p>	<p>1 foundation. Speculation.</p> <p>2 THE WITNESS: No, I cannot, Mr. Stanoch.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. You cannot tell me why Novartis would have 5 a method for detecting NDMA in ZHP's valsartan API, 6 can you?</p> <p>7 MS. LOCKARD: Objection. Outside the 8 scope of his class-certification opinions. Lacks 9 foundation. Calls for speculation.</p> <p>10 THE WITNESS: No, I can't, Mr. Stanoch.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Why would -- strike that. Start over.</p> <p>13 Why would Novartis be testing ZHP's 14 valsartan API for NDMA in the first place?</p> <p>15 MS. LOCKARD: Objection. Outside the 16 scope of his class-certification opinions. Calls 17 for speculation. Lacks foundation.</p> <p>18 THE WITNESS: I just have no idea, 19 Mr. Stanoch. It would be guessing, and I could only 20 guess.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Well, there is no specification in the 23 Diovan monograph, for example, for nitrosamines, 24 right?</p> <p>25 A. When you say "Diovan monograph," I assume</p>

<p>1 you are talking about the USP monographs for 2 valsartan API and valsartan drug product, and if 3 that's what we are talking about, Mr. Stanoch, there 4 are no tests for nitrosamine in those monographs. 5 Q. That would be for both the branded Diovan 6 product as well as generic valsartan products, 7 correct? 8 A. I think you are saying that correctly, 9 Mr. Stanoch, that USP doesn't distinguish between 10 manufacturers. The monographs are supposed to apply 11 to all manufacturers of the named article. 12 Q. When you refer in your report to 13 compendial requirements, what do you mean? 14 A. Well, in brief, I think, as we have 15 already discussed, we're talking about the 16 monographs, in this case, for valsartan drug 17 substance and valsartan drug product. 18 Q. Right. And you have looked at a couple of 19 monographs for valsartan, correct? 20 A. Yes, I think they were part of the 21 information I looked at, and I think they are in my 22 materials considered. And I'm glad to talk about 23 them if you wish, Mr. Stanoch. 24 Q. Of course. Would you agree that 25 compendial requirements includes the general USP</p>	<p>Page 126</p> <p>1 February 2021. 2 Q. I apologize. That's correct. I agree 3 with you there. 4 I'm going to mark an exhibit. Stand by, 5 sir. 6 (Whereupon, Exhibit 7 was marked for 7 identification.) 8 BY MR. STANOCHE: 9 Q. Stand by. 10 Okay. Exhibit 7, sir, has now been 11 marked. It also should be Tab 17 in your binder if 12 you would like to look at the hard copy. Tell me 13 when you are there. 14 A. Yes, I'm looking at it, Mr. Stanoch. 15 I'm -- 16 Q. Excellent. And this appears to be a copy 17 of the valsartan USP monograph printed January 28th, 18 2022. Do you see that? 19 A. Yes, and -- okay. Yes, I'm prepared to 20 discuss. 21 Q. Very good. So this would be an example of 22 a USP monograph that we were talking moments ago, 23 correct? 24 A. Exactly. 25 Q. All right. And this monograph is for</p>
<p>Page 127</p> <p>1 chapters? 2 A. Yes, the way I would say it is there is 3 general notices, which appear at the front of USP 4 and are generally applicable, and then a monograph 5 can reference general chapters that give detailed 6 information about a particular test or procedure. 7 Q. Got it. So it's fair to say, then, that 8 compendial requirements includes a drug monograph, 9 general notices and requirements, and conformance to 10 standards? 11 A. Yes. And if a monograph references a 12 general chapter, that would be part of the 13 monograph. 14 Q. And those also would include notices on 15 impurities, correct? 16 A. My sense is that impurities are a 17 universal test and should be present in most, if not 18 all, drug-substance and drug-product monographs, and 19 that would certainly be true of the valsartan 20 monographs. 21 Q. Uh-huh, uh-huh. And we talked earlier 22 that the FDA nitrosamine impurities guidance, I 23 think you said, was updated last September 2021? 24 A. Well, it appeared first in draft in 25 September '20, and then it was updated in</p>	<p>Page 129</p> <p>1 valsartan, correct? 2 A. Yes. 3 Q. And the date of this is current official 4 from last month, so this was after the FDA's last 5 turn of its nitrosamine impurities guidance in 6 February 2021, right? 7 A. I'm not sure I understood what you said. 8 It says, "Official Date: Official as of" May 1, 9 2020. Are we looking at the same thing? 10 Q. Right. And "Official Status" right above 11 that, sir, "Official Status: Currently Official on 12 28-Jan-2022." You see that? 13 A. I do, and that would be about a year after 14 the nitrosamine guidance. 15 Q. I can agree with that. And do you see any 16 mention of a test for nitrosamines in this valsartan 17 monograph? 18 A. All right. Now hold on just a sec. Okay. 19 When we get to "Impurities," I see, "Procedure 1: 20 Limit of Valsartan Related Compound A." "Procedure 21 2: Limit of Valsartan Related Compound B, Valsartan 22 Related Compound C, and Other Related Compounds." 23 And that's all I see. I do not see tests for 24 nitrosamine impurities. 25 Q. Do you see any reference to acceptable</p>

<p>1 limits for nitrosamines in this monograph?</p> <p>2 A. I do not.</p> <p>3 Q. Do you see any mention whatsoever of</p> <p>4 nitrosamines in this valsartan monograph?</p> <p>5 A. I don't believe -- I do not, Mr. Stanoch.</p> <p>6 Please correct me if you think I'm wrong.</p> <p>7 Q. No, I think you are correct. I just</p> <p>8 wanted to make sure we're on the same page. I don't</p> <p>9 see any mention of nitrosamines whatsoever in this</p> <p>10 monograph, and it sounds like you agree with me,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. So if a drug manufacturer made valsartan</p> <p>14 exactly per this monograph, they wouldn't</p> <p>15 necessarily be doing anything to test or control for</p> <p>16 NDMA, would they?</p> <p>17 A. If they just followed the monograph, I</p> <p>18 think I would agree with you.</p> <p>19 Q. Right. Following a monograph alone would</p> <p>20 not mean that a product was complying with the FDA's</p> <p>21 nitrosamine impurity guidance and limits, correct?</p> <p>22 A. Oh, I'm sorry. I'm hesitating a little</p> <p>23 bit because you alluded back to the nitrosamine</p> <p>24 impurities guidance.</p> <p>25 Q. Well, I'll withdraw the question and I'll</p>	<p>Page 130</p> <p>1 that specifically applies to a genotoxic impurity</p> <p>2 such as nitrosamines.</p> <p>3 Q. Uh-huh. Uh-huh. As of the date of this</p> <p>4 valsartan monograph, January 28, 2022, if a</p> <p>5 manufacturer followed it exactly, it would have no</p> <p>6 way of testing and identifying nitrosamines in the</p> <p>7 product, correct?</p> <p>8 MS. LOCKARD: Objection. Vague.</p> <p>9 THE WITNESS: I think I'll agree with you,</p> <p>10 Mr. Stanoch.</p> <p>11 BY MR. STANOCHE:</p> <p>12 Q. So whether a product was made according to</p> <p>13 a USP monograph or not does not definitively speak</p> <p>14 to whether the product contains nitrosamines,</p> <p>15 correct?</p> <p>16 A. Well, remember, you don't make a product</p> <p>17 according to a monograph. This is a monograph that</p> <p>18 has tests, procedures, acceptance criteria, that if</p> <p>19 you -- I'm trying to get into the USP</p> <p>20 understanding -- if your drug substance conforms to</p> <p>21 all these tests, then you can confirm that you have</p> <p>22 valsartan.</p> <p>23 Now, as you are discussing, and I agree</p> <p>24 with you, it doesn't say, does your valsartan have</p> <p>25 nitrosamine impurities that are adequately</p>
<p>Page 131</p> <p>1 phrase it again. Following this monograph alone to</p> <p>2 manufacture valsartan would not have any specified</p> <p>3 way of identifying and controlling nitrosamines,</p> <p>4 correct?</p> <p>5 A. I think you are -- yes, I agree with you,</p> <p>6 Mr. Stanoch.</p> <p>7 Q. Uh-huh. So the fact that a drug complies</p> <p>8 with a USP monograph alone does not mean the drug is</p> <p>9 free of any nitrosamine impurities?</p> <p>10 A. Yes, I think you are right. That ability</p> <p>11 to control nitrosamine would come up in the</p> <p>12 application to FDA and the FDA review. It would not</p> <p>13 be in the USP monograph.</p> <p>14 Q. Okay. And the USP is not responsible for</p> <p>15 identifying genotoxic impurities in drug product or</p> <p>16 drug substance, right?</p> <p>17 A. No, I agree with your -- that to me is</p> <p>18 more a regulatory matter.</p> <p>19 Q. All right. USP believes companies are</p> <p>20 responsible for identifying and assessing genotoxic</p> <p>21 impurities in their drug product or substance,</p> <p>22 correct?</p> <p>23 A. Yes. It's up to the manufacturer working</p> <p>24 with FDA to detect -- I'm trying to think of the</p> <p>25 string of words -- report, identify, qualify, and</p>	<p>Page 133</p> <p>1 controlled? That is a separate matter that is</p> <p>2 adjudicated by FDA.</p> <p>3 Q. Uh-huh. And USP general notices and</p> <p>4 requirements may also guide a manufacturer on how to</p> <p>5 identify nitrosamine impurities, correct?</p> <p>6 A. Well, yeah, there may be some statements</p> <p>7 in there that are very general statements, for</p> <p>8 example, that you have to follow GMPs, and GMPs may</p> <p>9 say, yes, you have to think about a genotoxic</p> <p>10 impurity.</p> <p>11 And I have heard it said, although I</p> <p>12 haven't seen it, Mr. Stanoch, I have heard that USP</p> <p>13 has general chapters on how to measure nitrosamine</p> <p>14 impurities.</p> <p>15 Q. Uh-huh.</p> <p>16 A. But I can't confirm that. I just heard</p> <p>17 it. Maybe you are aware of it and I'm not.</p> <p>18 Q. And is that discussed anywhere in your</p> <p>19 report, sir?</p> <p>20 A. No, not at all. And as a matter of fact,</p> <p>21 this monograph is not discussed in my report. I</p> <p>22 think I am talking about monographs that were</p> <p>23 official at the time of the 2018 time period.</p> <p>24 Q. So, well, we can pull those up too,</p> <p>25 Doctor. But if someone followed the USP monograph</p>

<p style="text-align: right;">Page 134</p> <p>1 for valsartan products in the 2018 time period, so 2 too they would have nothing from the monograph 3 itself about identifying nitrosamines, correct? 4 A. Yes. I agree with that, Mr. Stanoch. 5 Q. Uh-huh. That does not mean, though, that 6 the drug ultimately might not contain any 7 nitrosamines, right? 8 A. Or that they might be controlled in 9 another way. 10 Q. Correct. And it may be that even if a 11 valsartan product was made according to the 2018 12 monograph, that the drug could still be adulterated 13 under FDA regulations? 14 MS. LOCKARD: Objection. Vague. 15 Speculation. 16 THE WITNESS: I'm struggling a little bit 17 with what you said. Now, if you are citing the act, 18 I think we would say it was not adulterated 19 according to the provisions of the act that talk 20 about a USP standard, but it could be adulterated 21 under a private specification, which is allowed in 22 the act in the citation I provided. 23 BY MR. STANOCHE: 24 Q. Uh-huh. 25 A. Or it could be part of a GMP violation.</p>	<p style="text-align: right;">Page 136</p> <p>1 requirements. Is that okay? 2 A. Okay. 3 Q. Is that an accurate articulation of a 4 product, that it can meet compendial requirements? 5 A. It seems to me you are making a statement 6 about a hypothetical, and I don't disagree with your 7 hypothetical. 8 Q. Okay. So let's say there is a drug that 9 meets all compendial requirements, but it contains 10 anthrax. Is that drug adulterated? 11 MS. LOCKARD: Objection. Speculation. 12 MR. STANOCHE: I can ask a hypothetical, 13 Counsel. 14 Q. Go ahead, Dr. Williams. 15 MS. LOCKARD: Incomplete hypothetical. 16 Objection. 17 THE WITNESS: You know, it's a 18 hypothetical, and I would say, yes, it's got an 19 unacceptable contaminant. 20 BY MR. STANOCHE: 21 Q. Let's say a different, slightly different 22 hypothetical. Say a drug met all compendial 23 requirements but there was rat poison in it. Can it 24 be adulterated? 25 MS. LOCKARD: Objection. Calls for</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. Let's take examples of some other drugs, 2 Dr. Williams. Let's take an example of a drug that 3 was made according to USP compendial standards. You 4 with me so far? 5 A. I'm a little hesitant to talk about making 6 a drug according to the standards because USP does 7 not give process steps. So you might make a drug 8 according to your process steps and then test it 9 according to a USP monograph. 10 Q. Uh-huh. Well, that's a fair point, 11 Doctor, that a manufacturer's individual process may 12 have issues arise through it that are not covered by 13 the monograph itself. 14 A. Yes, exactly. 15 Q. Right. And it would be incumbent on the 16 manufacturer to understand its own individual 17 process and to assess the potential for any 18 impurities in the product even if the manufacturer 19 is otherwise following the monograph, right? 20 A. I agree with the way you stated that. 21 Thank you. 22 Q. Okay. And so let me go back to my 23 example. I'll try to think -- I'll try to phrase it 24 more accurately for you. 25 Let's take a drug that met all compendial</p>	<p style="text-align: right;">Page 137</p> <p>1 speculation. Incomplete hypothetical. 2 THE WITNESS: Again, I would say it has a 3 unacceptable contaminant. 4 BY MR. STANOCHE: 5 Q. Even though the compendial requirements 6 may not have a test for rat poison, correct? 7 A. Exactly. 8 Q. Uh-huh. And let's take another example. 9 Let's say there is a drug that met all compendial 10 requirements, but broken glass are in the capsules. 11 Could it be adulterated? 12 MS. LOCKARD: Objection. Speculation. 13 Incomplete hypothetical. 14 THE WITNESS: Well, it could be 15 adulterated according to GMPs, but I think it could 16 not be adulterated according to the compendial 17 standard in the act. 18 I have got another good example, which is 19 the tampering of the Tylenol many years ago where 20 somebody put needles in the bottles. I don't know 21 if you remember that, Mr. Stanoch. Do you recall 22 that? 23 BY MR. STANOCHE: 24 Q. No, I don't. 25 A. Well, FDA went to great trouble working</p>

<p>1 with a highly responsible manufacturer to get that 2 product off the shelves.</p> <p>3 Q. And was that product considered 4 adulterated because of the presence of needles in 5 the bottles?</p> <p>6 A. I think you could probably say that it was 7 a GMP failure of some kind, but --</p> <p>8 Q. Uh-huh.</p> <p>9 A. At a certain point in time, FDA could take 10 action, you know, as it deems appropriate for public 11 health.</p> <p>12 Q. Uh-huh. And in your example of the 13 Tylenols with needles in the bottle, did a consumer 14 who got a bottle with a needle in it before any FDA 15 action, were they holding an adulterated product?</p> <p>16 A. I can't remember the details. I think you 17 are asking sort of a speculative question. I think 18 you could say it was adulterated because of failure 19 of GMPs.</p> <p>20 Q. But you could --</p> <p>21 A. You know, FDA has broad authority to 22 remove adulterated products from the market. I can 23 say that.</p> <p>24 Q. Sure. I would agree with that. But you 25 can have a product, in this example we're talking</p>	<p>Page 138</p> <p>1 what is there according to tests, procedures, and 2 acceptance criteria. It couldn't possibly assess 3 all the possible negative things that might be 4 there.</p> <p>5 Q. Right. And in this example, assuming you 6 have a product that met all compendial requirements 7 except it also contained anthrax, the consumer 8 holding that product is holding an adulterated 9 product prior to any FDA action against that 10 manufacturer, fair?</p> <p>11 A. Yes. And as long as we're staying with 12 these hypotheticals, I can say a valsartan monograph 13 could have an impurity procedure for nitrosamines. 14 Of course, it would take very specialized equipment, 15 and it might have the limits set by FDA via the 16 guidance. So there is nothing precluding that.</p> <p>17 Q. So --</p> <p>18 A. And I'm not exactly sure why it hasn't 19 occurred, but maybe companies are figuring out a way 20 to keep their manufacturing process such that the 21 limits are met without testing.</p> <p>22 Q. Okay. And you have not seen any USP 23 monograph for valsartan that contains any impurity 24 procedures for nitrosamines, right?</p> <p>25 A. I have not.</p>
<p>Page 139</p> <p>1 about, the consumer's holding a bottle of Tylenol 2 with needles in it. That product they are holding 3 is adulterated even prior to an FDA action against 4 the manufacturer, is it not?</p> <p>5 A. I think you could say that. I think 6 people wouldn't quibble with that designation.</p> <p>7 Q. Okay. You can say the same with sort of 8 the other examples. For example, I mean, we talked 9 about a drug made to compendial requirements that 10 contained anthrax. That drug in a consumer's hand 11 would be adulterated prior to the FDA taking 12 official action against the manufacturer, correct?</p> <p>13 MS. LOCKARD: Objection. Speculation.</p> <p>14 Incomplete hypothetical.</p> <p>15 THE WITNESS: Yeah, I -- I'm sorry. I 16 have lost track of your question. The hypothetical 17 that the product has been willfully adulterated?</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. The question simply was another example. 20 I'll say it again. Assume you have a product that 21 met all compendial requirements, except it also 22 contained anthrax. You with me?</p> <p>23 A. Yes. I think you are making general 24 statements that are quite true, Mr. Stanoch, that 25 the compendial standard really is designed to assess</p>	<p>Page 141</p> <p>1 Q. Uh-huh.</p> <p>2 MS. LOCKARD: We have been going about an 3 hour since the last break, so whenever you get to a 4 stopping point, I would like a break.</p> <p>5 MR. STANOCH: Now is fine.</p> <p>6 Doctor, would you like to take a break?</p> <p>7 THE WITNESS: That would be nice,</p> <p>8 Mr. Stanoch. Thank you.</p> <p>9 MR. STANOCH: Let's do it. Great.</p> <p>10 THE VIDEOGRAPHER: Great. Then we are 11 going off the record. The time is 10:49.</p> <p>12 (Whereupon, a brief recess was taken.)</p> <p>13 THE VIDEOGRAPHER: Okay. We are coming 14 back on the record. The time on the video monitor 15 is 11:07. Please begin.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Welcome back, Dr. Williams.</p> <p>18 A. Hi, Mr. Stanoch.</p> <p>19 Q. Did you talk with anyone besides your 20 counsel during the break?</p> <p>21 A. No, I did not.</p> <p>22 Q. Did you talk with your counsel during the 23 break?</p> <p>24 A. Yes, I did.</p> <p>25 Q. And did you look at any documents during</p>

<p>1 the break?</p> <p>2 A. We sort of looked through the documents in 3 the binder you provided, but we didn't review any. 4 And we didn't get through all the documents. There 5 were a few at the end we didn't look at, at all.</p> <p>6 Q. You flipped through the binder of 7 potential exhibits?</p> <p>8 A. Yes.</p> <p>9 MS. LOCKARD: Just very briefly.</p> <p>10 MR. STANOCH: Counsel, I'm going to --</p> <p>11 MS. LOCKARD: We didn't go through these 12 documents.</p> <p>13 MR. STANOCH: Counsel, and I didn't think 14 I needed to state this, but I'll put on the record, 15 I object to you flipping through the courtesy binder 16 of potential exhibits we prepared at your request 17 for the convenience of the witness.</p> <p>18 Not all of them may be used. We want them 19 not to be looked at, certainly to be destroyed 20 without looking at them, the witness or counsel, 21 especially when we're doing it as a courtesy to you 22 and the witness, when we have asked for similar 23 courtesies from your side, not you, Counsel, but 24 other counsel on your side, we have been flat-out 25 rejected when we have asked for hard copies.</p>	<p>Page 142</p> <p>1 an exhibit is marked. Thank you.</p> <p>2 MS. LOCKARD: That's fine. You may have 3 to give me a moment to find the document in hard 4 copy if I need to. So --</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Did you look at any other documents, 7 Doctor, during the break?</p> <p>8 A. No, no other documents.</p> <p>9 Q. Okay. Doctor, would you agree that if a 10 manufacturer controls impurities and degradation 11 products in accordance with only a pharmacopeial 12 monograph, that is acceptable to regulators?</p> <p>13 A. I think it can be, yes. If it is a good 14 monograph, it can be sufficient to control the 15 product in the marketplace.</p> <p>16 Q. What if the individual monograph is 17 inadequate to control an impurity?</p> <p>18 A. If we're talking about the nitrosamine, I 19 would say then there needs to be additional 20 requirements that are private, agreed to with FDA.</p> <p>21 Q. Uh-huh. Well, what agreements with FDA 22 does any valsartan manufacturer have today, given 23 that we looked at the valsartan monograph and there 24 is nothing about nitrosamines in it?</p> <p>25 A. Well, I can only speak to Teva, and the</p>
<p>Page 143</p> <p>1 So it's very troubling to me that you are 2 looking through all potential exhibits we provided, 3 and I would ask that that not happen again, now or 4 at a future deposition.</p> <p>5 MS. LOCKARD: As the witness said, we did 6 not discuss these documents. I'm trying to make 7 sure I have copies of them in hand. We have one 8 binder here that I'm having to walk over and look 9 over Dr. Williams' shoulder, so --</p> <p>10 MR. STANOCH: Every single document I 11 marked from the binder, Counsel, is also put up on 12 the screen for all counsel on the Zoom to see. So I 13 would just ask that no one looks at the binder until 14 the witness is directed to do it. Thank you.</p> <p>15 MS. LOCKARD: Well, I would like to have 16 hard copies in my hand because on some of these we 17 don't even have the full document up on the screen, 18 just showing pages.</p> <p>19 MR. STANOCH: Well, first of all, that 20 wasn't the request. It was for your witness.</p> <p>21 Second of all, when we have asked for the 22 same thing for our witness, let alone us, we have 23 been flat-out refused by some on your side, not you. 24 So going forward, we can talk about this, but again, 25 for now I'm asking, do not look at the binder until</p>	<p>Page 145</p> <p>1 answer to that is clear, there are no Teva valsartan 2 products in the U.S. marketplace. As we have 3 already discussed, Teva immediately recalled them -- 4 "immediately" can be a little debatable -- when the 5 impurities were discovered.</p> <p>6 Q. Uh-huh. Is it incumbent on the 7 manufacturer that discovers an impurity to develop 8 and validate appropriate analytical procedures, 9 establish acceptance criteria, and communicate with 10 USP?</p> <p>11 A. There is no obligation for a manufacturer 12 to work with USP at all. That's voluntary.</p> <p>13 Q. Uh-huh.</p> <p>14 A. I would say there is a requirement to do 15 so with FDA if you come to the private 16 specification.</p> <p>17 Q. I'm going to mark the next exhibit. Stand 18 by.</p> <p>19 (Whereupon, Exhibit 8 was marked for 20 identification.)</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. I have marked Exhibit 8, Doctor, it's 23 actually Tab 12 in your -- tell me when you're 24 there, sir.</p> <p>25 (Reporter clarification.)</p>

<p style="text-align: right;">Page 146</p> <p>1 BY MR. STANOCHE:</p> <p>2 Q. Binder. Tell me when you are there.</p> <p>3 A. Okay. I have been handed Tab 12, which</p> <p>4 looks like it's about 20 or 30 pages of a USP</p> <p>5 webcast. So I'm there, Mr. Stanoch.</p> <p>6 Q. Very good. And this is a USP presentation</p> <p>7 entitled "Impurities in Drug Products and Drug</p> <p>8 Substances - A USP Approach," yes?</p> <p>9 A. Yes.</p> <p>10 Q. And you see the last update on the first</p> <p>11 page is March 2018, right?</p> <p>12 A. Wait a minute. I'm trying to find</p> <p>13 March 2018. Where is that?</p> <p>14 Q. Slide 1, lower left, light gray text.</p> <p>15 A. Yes, it's very faint in my print, but yes,</p> <p>16 I can see it. Thank you, Mr. Stanoch.</p> <p>17 Q. Not a problem. It's faint in mine too and</p> <p>18 in the original. That's why I was happy to draw</p> <p>19 your attention to it.</p> <p>20 So this is prior to the valsartan recalls</p> <p>21 that began in the summer of 2018, right?</p> <p>22 A. March 2018. Okay. I'm with you. Yes.</p> <p>23 Thank you. I agree.</p> <p>24 Q. Good. Let's flip to Slide 36. So if you</p> <p>25 are looking at the little page numbers in the lower</p>	<p>1 may lead to different impurities."</p> <p>2 Did I read that right?</p> <p>3 A. Yes, you read that correctly.</p> <p>4 Q. Do you agree with that statement?</p> <p>5 A. I do agree with it.</p> <p>6 Q. Then it also reads, "If an individual</p> <p>7 monograph is inadequate to control an impurity, the</p> <p>8 manufacturer is responsible for developing and</p> <p>9 validating appropriate analytical procedures,</p> <p>10 establishing acceptance criteria, and communicating</p> <p>11 with USP."</p> <p>12 Did I read that right?</p> <p>13 A. Yes, you did. And I agree with that</p> <p>14 statement.</p> <p>15 Q. Okay. So what USP is advising in this</p> <p>16 slide is that it's -- the onus on the manufacturer</p> <p>17 to understand and evaluate its own process and any</p> <p>18 impurities that may arise in that process for a</p> <p>19 drug, correct?</p> <p>20 A. Yes, I think you are stating it correctly.</p> <p>21 Q. Uh-huh. If you can flip to the slide --</p> <p>22 page 63. Let me know when you are there.</p> <p>23 A. Okay. I'm on page 63, top of the page.</p> <p>24 Q. Great. And it says, "Setting Acceptance</p> <p>25 Criteria for Impurities," right?</p>
<p style="text-align: right;">Page 147</p> <p>1 right, it would be the page that has Slides 35 and</p> <p>2 36 on it.</p> <p>3 A. 34. So I am looking at 35 and 36. Yes,</p> <p>4 I'm there.</p> <p>5 Q. Okay. You see there is a Q and A on Slide</p> <p>6 36, correct?</p> <p>7 A. I do see that.</p> <p>8 Q. And the question is: "If a manufacturer</p> <p>9 controls impurities and degradation products in</p> <p>10 accordance with only a pharmacopeial monograph, is</p> <p>11 that acceptable to the regulators?" Did I read that</p> <p>12 right?</p> <p>13 A. Yes, you did.</p> <p>14 Q. Then there is a three-bullet answer,</p> <p>15 correct?</p> <p>16 A. Yes, I do see that.</p> <p>17 Q. Okay. And it notes first the monographs</p> <p>18 are based on historic preparation, right?</p> <p>19 A. Yes. I'm not exactly sure what that</p> <p>20 means, but you are reading it correctly.</p> <p>21 Q. And then the next bullet notes that, "A</p> <p>22 particular manufacturer's manufacturing method for</p> <p>23 formulation components may lead to unexpected</p> <p>24 impurities, due to a different route of synthesis,</p> <p>25 different reagents, et cetera. Different processes</p>	<p>1 A. Yes.</p> <p>2 Q. And there is three bullets there?</p> <p>3 A. Yes, I see that.</p> <p>4 Q. Let me direct your attention to the third</p> <p>5 bullet. Are you there?</p> <p>6 A. Yes.</p> <p>7 Q. And read the first sentence for us.</p> <p>8 A. "If a limit for a specified impurity does</p> <p>9 not exist in the USP, FDA recommends that you</p> <p>10 qualify the impurity by comparing it to the observed</p> <p>11 amounts of the impurity in the reference listed</p> <p>12 drug. Your acceptance criterion should be similar</p> <p>13 to the level observed in the" reference listed drug.</p> <p>14 "Alternatively, the acceptance criteria may be set</p> <p>15 based on a qualified level that is justified by</p> <p>16 scientific literature, metabolite data, or toxicity</p> <p>17 studies."</p> <p>18 Q. Do you agree with that statement?</p> <p>19 A. I do.</p> <p>20 Q. Uh-huh. So the event that, say, a</p> <p>21 valsartan USP monograph did not contain a limit for</p> <p>22 a nitrosamine, the recommendation would be for the</p> <p>23 manufacturer to qualify the impurity, correct?</p> <p>24 A. If the impurity existed in their product,</p> <p>25 I think you could make that claim.</p>

<p>1 Q. Do you know if, prior to the summer of 2 Teva ever made any effort to qualify any 3 nitrosamine impurity in its valsartan products? 4 A. I think they did not. They did not 5 suspect them, and their analytical tests in their 6 private or public specification wouldn't have picked 7 up a nitrosamine impurity. 8 Q. Uh-huh. Again, though, you don't know 9 like what tests Teva in particular might have been 10 employing for valsartan at the time, right? 11 A. Well, it seems to me we could assume they 12 were following the USP monograph for valsartan -- 13 Q. Uh-huh. 14 A. -- and valsartan drug product. 15 Q. Uh-huh. But you don't know how Novartis 16 was able to detect NDMA in valsartan API whereas 17 Teva did not? 18 MS. LOCKARD: Objection. Asked and 19 answered. 20 THE WITNESS: Yeah, that is sort of a 21 different set of questions. And Novartis would have 22 been following the monograph, too, for valsartan and 23 valsartan drug product if it existed. 24 BY MR. STANOCH: 25 Q. Well, that's sort of the point, Doctor,</p>	<p>Page 150</p> <p>1 wanted on another product for a myriad of reasons, 2 but I just don't have any information about what 3 Novartis was doing with the ZHP product. 4 BY MR. STANOCH: 5 Q. You look on the next page, on 65, sir. 6 Tell me when you are there. 7 A. Yes. Top of the page? 8 Q. Yes. It reads, "USP General Chapters for 9 Impurities: <476> & <1086>"? 10 A. Yes, I do see that. 11 Q. And these are examples of general chapters 12 in the USP that would be part of so-called 13 compendial requirements, correct? 14 A. Yes. I think we have alluded to this 15 before in our prior discussion. 16 Q. Thank you. You can put that aside for 17 now. 18 I'm going to mark the next exhibit. Stand 19 by, sir. 20 (Whereupon, Exhibit 9 was marked for 21 identification.) 22 BY MR. STANOCH: 23 Q. This will be Exhibit 9. It's Tab 13 in 24 your binder, sir. Tell me when you are there. 25 A. Okay. I'm seeing it. It, again, is a USP</p>
<p>Page 151</p> <p>1 that Novartis, following the monograph that did not 2 contain any mention of nitrosamines, nonetheless did 3 a test that detected the nitrosamines, right? 4 MS. LOCKARD: Objection. Lacks 5 foundation. Speculation. Outside the scope of his 6 opinions. 7 THE WITNESS: Yeah, I have already stated, 8 Mr. Stanoch, I have no understanding of what 9 Novartis was doing. 10 BY MR. STANOCH: 11 Q. Would you agree, though, that Novartis 12 performed some test that was not in the monograph 13 that detected the nitrosamines, correct? 14 MS. LOCKARD: Objection. Speculation. 15 Lacks foundation. Outside of his opinions in the 16 class-certification report. 17 THE WITNESS: I think what I was trying to 18 say is that when Novartis released its Diovan into 19 the U.S. market, it would try to make sure it 20 conformed to the USP valsartan and valsartan 21 drug-product monographs. Those monographs, as I 22 have already said, apply to brand and generic 23 manufacturers. 24 Now, speaking hypothetically, any company, 25 including Novartis, could do any kind of testing it</p>	<p>Page 153</p> <p>1 document. 2 Q. Correct. 3 A. "Overview of" -- "General Chapters <476> 4 and <1086>." 5 Q. Yes, sir. And the date on that document? 6 A. Another visual acuity test. I don't 7 see -- 8 Q. I see October 19th, 2017, right on the 9 title page. 10 A. Oh, right, yeah. Right. Thank you. 11 Q. Is that right? 12 A. Yes, exactly, thank you. 13 Q. Oh, good. No problem. And have you seen 14 this -- actually -- strike that. 15 Have you seen the last exhibit prior to 16 today, sir? 17 A. No, I haven't, nor this one. 18 Q. Thank you. Okay. So let's flip to page 19 13, sir. Tell me when you are there. 20 A. And where will I see the page numbers? 21 Q. Oh, it's the lower right of the pages. 22 The title is, "Manufacturers responsibilities in 23 <1086> and <476>." 24 A. Okay. I'm there. I see it. 25 Q. Okay. In this slide in the USP</p>

<p>1 presentation, sets forth what it says are 2 "Manufacturer's Responsibilities in General Chapter 3 <1086>" and "Manufacturer's Responsibilities in 4 General Chapter <476>." Do you see that? 5 A. I do see that. 6 Q. And then why don't you read that first 7 bullet that begins, "If a new impurity"? 8 A. "If a new impurity is detected above the 9 appropriate identification threshold or when the 10 level of a specified related compound increases as 11 compared to its characteristic impurity profile, the 12 manufacturer is responsible for evaluating the 13 impact on the safety and efficacy of the drug 14 substance or drug product." 15 Shall I continue? 16 Q. Do you agree with that -- no, why don't 17 you -- just that bullet. Do you agree with that 18 statement, sir? 19 A. Yes, I do. 20 Q. Okay. Why don't you read the second 21 bullet. 22 A. "For marketed products, the manufacturers 23 are responsible for controlling organic impurities 24 in accordance with current regulatory standards." 25 Q. Do you agree with that statement, sir?</p>	<p>Page 154</p> <p>1 that statement you just read. Do you agree with 2 that statement, sir? 3 A. I do agree with it. 4 Q. And could you read the final bullet, sir? 5 A. Right. "Manufacturers shall develop 6 acceptance criteria for impurities justified by 7 appropriate safety considerations and consistent 8 with current applicable regulatory guidances." 9 Q. Do you agree with that statement as well, 10 sir? 11 A. I do. 12 Q. Okay. Thank you. Let's put that aside 13 for now. Stand by for the next exhibit. 14 (Whereupon, Exhibit 10 was marked for 15 identification.) 16 BY MR. STANOCH: 17 Q. I am marking Exhibit 10. Sir, that should 18 be Tab 14 in your binder. Let me know when you are 19 there. 20 A. Yes, I'm there. 21 Q. Okay. This is a slide deck from the FDA. 22 You see that, sir? 23 A. I do. Dated October 2, 2020. 24 Q. Correct. And you see the two names of the 25 presenters there, Dr. -- is it Keire and Dr. Lu?</p>
<p>Page 155</p> <p>1 A. I do. 2 Q. Could you read the next one under the 3 subheading "Manufacturer's Responsibilities in 4 General Chapter <476>"? 5 A. The first bullet? 6 Q. Yes, sir. 7 A. "If an individual monograph is inadequate 8 to control does not include a procedure for 9 qualifying an impurity or acceptance criterion for 10 an observed impurity, the manufacturer is 11 responsible for developing and validating 12 appropriate analytical procedures and establishing 13 appropriate acceptance criteria." 14 Q. Do you agree with that statement, sir? 15 A. Yes, it seems -- I can agree with it. 16 Q. Could you kindly read the next one, sir? 17 A. "Manufacturers shall validate or verify, 18 as appropriate analytical procedures must 19 demonstrate their suitability for detection and 20 quantification of impurities in the drug substances 21 and drug products." 22 Q. Thank you. 23 A. "Manufacturers shall develop" -- oh, I'm 24 sorry. I went on. 25 Q. That's fine. Let's just stop there at</p>	<p>Page 155</p> <p>Page 157</p> <p>1 A. I do see those names. 2 Q. Did you work with them when you were at 3 the FDA? 4 A. I don't recognize these names. 5 Q. Quite all right. And have you seen this 6 slide presentation before, sir? 7 A. No, I haven't. 8 Q. Let's turn to page 3. Tell me when you 9 are there. 10 A. Is this the one that states, 11 "Pharmaceutical Quality"? 12 Q. Yes, sir. 13 A. Yes, I'm there. 14 Q. It states, "A quality product of any kind 15 consistently meets the expectations of the user," 16 correct? 17 A. Yes, I see that. 18 Q. And then flip to the next slide. You 19 there? 20 A. Yes. 21 Q. Now it says, "A quality product of any 22 kind consistently meets the expectations of the 23 user. Drugs are no different," correct? 24 A. I see that. 25 Q. Do you agree with that characterization of</p>

<p>1 pharmaceutical quality?</p> <p>2 MS. LOCKARD: Objection. Outside the</p> <p>3 scope of his class-certification opinions. Vague.</p> <p>4 THE WITNESS: I don't want to debate what</p> <p>5 the FDA is saying here, but I will say that users,</p> <p>6 sometimes including me, can be very uninformed about</p> <p>7 what the expectation for a product should be. But I</p> <p>8 don't want to debate it. You know, I certainly can</p> <p>9 agree with it generally.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Understood. And would you agree, though,</p> <p>12 that users of a drug have no way of knowing if the</p> <p>13 drug contains nitrosamines absent the disclosure by</p> <p>14 the manufacturer or regulator?</p> <p>15 MS. LOCKARD: Objection. Speculation.</p> <p>16 Vague.</p> <p>17 THE WITNESS: Yes, some kind of</p> <p>18 disclosure. And I think you were more specific</p> <p>19 about what I was trying to say. It's very hard for</p> <p>20 a user to understand what the quality expectations</p> <p>21 of a medicine are.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Uh-huh. And you can flip to the next page</p> <p>24 of the slide, sir.</p> <p>25 A. "Patients expect safe and effective"?</p>	<p>Page 158</p> <p>1 sir. You can tell me when you are there.</p> <p>2 A. Oh, wait. Okay. Yes, I'm on 9.</p> <p>3 Q. And here we see reference to the ICH M7</p> <p>4 guidance again?</p> <p>5 A. Yes, I do. Yes, exactly.</p> <p>6 Q. And again, there is reference to the</p> <p>7 nitroso compounds being part of a cohort of concern,</p> <p>8 right?</p> <p>9 A. Yes, I see that.</p> <p>10 Q. I think we established earlier, but you</p> <p>11 can correct me if I'm wrong, that we agree that the</p> <p>12 ICH M7 includes nitroso compounds in the so-called</p> <p>13 cohort of concern, right?</p> <p>14 MS. LOCKARD: Objection. Asked and</p> <p>15 answered. Outside the scope of his deposition.</p> <p>16 THE WITNESS: Yes. And this is a very</p> <p>17 general statement, but I see nothing to disagree</p> <p>18 with.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Go back to the slide we were looking at</p> <p>21 prior to this, the pharmaceutical quality slide.</p> <p>22 A. "Pharmaceutical quality is assuring every</p> <p>23 dose"?</p> <p>24 Q. Yes, sir.</p> <p>25 A. I'm there, Mr. Stanoch.</p>
<p>Page 159</p> <p>1 Q. Yes. Just read the sentence for me.</p> <p>2 A. "Patients expect safe and effective</p> <p>3 medicines with every dose they take."</p> <p>4 Q. As a general matter do you agree with</p> <p>5 that?</p> <p>6 MS. LOCKARD: Objection. Calls for</p> <p>7 speculation. Vague.</p> <p>8 THE WITNESS: Yeah, and it's very hard for</p> <p>9 me to know what patients really expect, but I</p> <p>10 certainly don't disagree generally with the</p> <p>11 statement.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Uh-huh. And then let's flip to the next</p> <p>14 page, sir.</p> <p>15 A. "Assuring every dose is safe"?</p> <p>16 Q. Yeah. Why don't you just read that whole</p> <p>17 statement there on the slide?</p> <p>18 A. "Pharmaceutical quality is assuring every</p> <p>19 dose is safe and effective, free of contamination</p> <p>20 and defects."</p> <p>21 Q. Uh-huh. Do you generally agree with that</p> <p>22 statement?</p> <p>23 A. Yeah, I don't see anything specifically</p> <p>24 objectionable.</p> <p>25 Q. Uh-huh. And if you can flip to page 9,</p>	<p>Page 161</p> <p>1 Q. Very good. Do you believe a valsartan</p> <p>2 drug that contained nitrosamines was safe and</p> <p>3 effective and free of contamination and defects?</p> <p>4 MS. LOCKARD: Objection. Outside the</p> <p>5 scope of his expert opinion for class certification.</p> <p>6 THE WITNESS: I'm sorry. Could you say</p> <p>7 the question again, Mr. Stanoch?</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Do you believe a valsartan drug that</p> <p>10 contained nitrosamines was safe and effective and</p> <p>11 free of contamination and defects?</p> <p>12 MS. LOCKARD: Same objection. And vague.</p> <p>13 THE WITNESS: Yeah. Speaking separate</p> <p>14 from my report, I think it's possible it could be</p> <p>15 free of contamination and defects, so I guess I'm</p> <p>16 answering yes to your question.</p> <p>17 BY MR. STANOCH:</p> <p>18 Q. And you opine that a, you know, recall is</p> <p>19 taken by companies to remove defective products in</p> <p>20 the market, correct?</p> <p>21 A. Yes. I would say that's the general</p> <p>22 purpose of a recall.</p> <p>23 Q. Uh-huh. Right. And so when Teva</p> <p>24 instituted its recalls for its valsartan products,</p> <p>25 it was removing defective drug product from the</p>

<p>1 market, correct?</p> <p>2 MS. LOCKARD: Objection. Outside the 3 scope of his opinion. Also vague and speculation. 4 Asking him to give legal opinion.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. I'm reading from your report, sir. There 7 is no speculation.</p> <p>8 A. Yeah, I would say Teva recalled its 9 valsartan-containing drug products because of 10 nitrosamine contamination.</p> <p>11 Q. Right. And that contamination is what 12 rendered them defective, making the voluntary recall 13 action appropriate?</p> <p>14 A. Well, but what --</p> <p>15 MS. LOCKARD: Same objections.</p> <p>16 THE WITNESS: The way I would say it, it 17 was -- I'm hesitating on the word "contamination." 18 The nitrosamines could be there within acceptable 19 limits. When -- but working with FDA, Teva recalled 20 even though the limits hadn't been set. I'm trying 21 to be specific in terms of what my report says.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Okay. And so let's slightly rephrase 24 that, then, to see if we get on the same page. You 25 write -- and you can look at Paragraph 69 of your</p>	<p>Page 162</p> <p>1 because of a defective product.</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. And is it your understanding that Teva 4 recalled all of its valsartan-containing drug 5 products in the summer of 2018?</p> <p>6 A. No. No. I think there was -- the recalls 7 in summer of 2018 were for the valsartan drug 8 products using ZHP drug substance. And then, based 9 on further information that came in over the fall, 10 FDA recalled its valsartan drug products containing 11 the Mylan product.</p> <p>12 Q. Right. Were you aware that Teva initially 13 instituted a hold on the marketing of all its 14 valsartan finished-dose products when it heard from 15 ZHP in late June 2018?</p> <p>16 A. Yes. I think I am aware of that, and I 17 think that's one of the documents -- there are two 18 documents I cite in that regard.</p> <p>19 Q. That is correct. And then shortly after 20 its hold, Teva lifted its hold on valsartan 21 finished-dose made with non-ZHP API, correct?</p> <p>22 A. Yes, I think you are stating it correctly, 23 because Teva had no reason to think that it had 24 objectionable nitrosamine impurity levels.</p> <p>25 Q. Right. And I'm going to put up a document</p>
<p>Page 163</p> <p>1 report if you would like -- "A recall is a voluntary 2 action taken by a company to remove a defective drug 3 product from the market"; is that right?</p> <p>4 A. All right. I'm going to my report.</p> <p>5 Q. Of course.</p> <p>6 A. Paragraph 69.</p> <p>7 Yes, I'm reading from my report, and I see 8 where you are reading, Mr. Stanoch.</p> <p>9 Q. And you characterize elsewhere in your 10 report that Teva's recalls of its valsartan products 11 were voluntary, that's what you say, right?</p> <p>12 A. Right, right.</p> <p>13 Q. And the defect behind the Teva voluntary 14 recalls of its valsartan products were the 15 nitrosamine impurities; is that right?</p> <p>16 MS. LOCKARD: Objection. Vague. Outside 17 of the scope of his report.</p> <p>18 THE WITNESS: Well, the way I would say it 19 is FDA and Teva working together agreed that the 20 levels of nitrosamine impurities were unacceptable. 21 But I have also alluded in my report that it was 22 unusual because neither FDA nor Teva at the time had 23 a specific limit as to what was unacceptable.</p> <p>24 But I don't think I'm debating you, 25 Mr. Stanoch. Let me agree that the recall was</p>	<p>Page 165</p> <p>1 just to help us with the timeline. Stand by, 2 Doctor.</p> <p>3 This will be Teva Exhibit 11. It should 4 be Tab 24 in your binder, sir. Let me know when you 5 are there.</p> <p>6 (Whereupon, Exhibit 11 was marked for 7 identification.)</p> <p>8 THE WITNESS: Should I put away the FDA 9 overview exhibit?</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Yes.</p> <p>12 A. Yes, I see this lift of hold dated July 6, 13 2018.</p> <p>14 Q. Very good. So this document appears to be 15 a Teva memo dated July 6, 2018, about lifting hold 16 status for certain valsartan products, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And so sometime prior to this Teva, as we 19 talked about, instituted a hold on all of its 20 valsartan products, right?</p> <p>21 A. Yes.</p> <p>22 Q. Right. And then as of July 6, 2018, Teva, 23 it appears, lifted its hold on valsartan 24 finished-dose products that used non-ZHP valsartan 25 API, correct?</p>

<p style="text-align: right;">Page 166</p> <p>1 A. Yes, I agree.</p> <p>2 Q. Uh-huh. And it looks like Teva had been 3 using valsartan API from Jubilant as well, correct?</p> <p>4 A. I would --</p> <p>5 MS. LOCKARD: Objection. Speculation.</p> <p>6 Foundation.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. You can look at the document, Doctor.</p> <p>9 A. I see the document. I wasn't aware that 10 the Teva valsartan products used Jubilant drug 11 substance.</p> <p>12 Q. Oh, I see. You also see that Teva lifted 13 the hold on valsartan products as of July 6, 2018, 14 that contained API from Mylan, correct?</p> <p>15 A. Yes, I do see that.</p> <p>16 Q. Okay. I think you alluded to that a few 17 questions ago, that you understood that Teva had 18 used Mylan API for some valsartan products sold in 19 the U.S., right?</p> <p>20 A. Yes, particularly the -- I'm trying to 21 think. These were the ones made in the Jerusalem 22 facility.</p> <p>23 Q. I would agree with that, sir, yes. I 24 think we're on the same page.</p> <p>25 Are you aware of any testing that Teva did</p>	<p style="text-align: right;">Page 168</p> <p>1 A. Well, my understanding of the sequence of 2 events is Mylan was saying it couldn't be in their 3 drug substance for valsartan, but Swissmedic did 4 some testing, and that's when Teva became aware that 5 there could be NDEA in the Mylan drug substance. 6 And that went to Teva's recall in November of 2018.</p> <p>7 Q. Uh-huh. Was it appropriate for Teva to 8 lift its hold on products without testing it?</p> <p>9 MS. LOCKARD: Objection. Outside the 10 scope of his class-certification report.</p> <p>11 THE WITNESS: Well, I don't know that they 12 didn't test it, so I can't respond to that question.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Uh-huh. Are you aware of whether tests 15 had been developed after June 2018 to detect 16 nitrosamines?</p> <p>17 A. Well, the FDA was working on tests, and I 18 think Teva was as well. And I think Teva's test 19 didn't come along -- online until later, but I don't 20 have those facts readily available now.</p> <p>21 Q. Right. Right. Are you aware that, at the 22 very least, the FDA announced in the summer of 2018 23 that it had found NDEA in a different manufacturer, 24 Torrent's valsartan products?</p> <p>25 A. I am actually not aware of that.</p>
<p style="text-align: right;">Page 167</p> <p>1 of its own finished dose that -- just let me start 2 over.</p> <p>3 Are you aware of any testing that Teva did 4 of its own finished dose that contained API from 5 Mylan prior to its lifting the hold?</p> <p>6 MS. LOCKARD: Objection. Vague.</p> <p>7 THE WITNESS: I am not.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Are you aware of whether Mylan tested 10 valsartan API that it was selling to Teva prior to 11 Teva's lifting its hold?</p> <p>12 A. You know, I have a feeling that there may 13 be some documentation in the materials considered, 14 but I'm not aware of it and I didn't cite it in my 15 report.</p> <p>16 Q. Did Teva ever test its own valsartan 17 finished dose that contained API from Mylan prior to 18 Teva's recalling that product later in 2018?</p> <p>19 MS. LOCKARD: Objection. Vague.</p> <p>20 THE WITNESS: I just can't say. I didn't 21 cite it in my report, so I don't know.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Do you know when, if at all, Mylan tested 24 valsartan API it was selling to Teva for 25 nitrosamines after this July 6, 2018, hold memo?</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. Uh-huh. And I can certainly pull up the 2 notice, but the FDA said that Torrent products were 3 included in the company's recall in August 23rd, 4 2018. Were you aware of that?</p> <p>5 A. I'm sure I looked at it, but I'm not 6 specifically aware of it until you mention it now, 7 Mr. Stanoch.</p> <p>8 Q. Uh-huh. You would agree, then, that if 9 the FDA was testing and finding NDEA in a different 10 manufacturer's product, there were testing methods 11 available to determine NDEA by August 2018, correct?</p> <p>12 MS. LOCKARD: Objection. Speculation.</p> <p>13 Vague. And outside the scope of his report.</p> <p>14 THE WITNESS: Yeah, I just don't have 15 information to answer the question.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Uh-huh. Can you say one way or the other 18 whether Teva ever tested any of its own product for 19 NDEA prior to its November 2018 recalls?</p> <p>20 A. I am sure that information exists, but I 21 don't have it -- I didn't cite it in my report and I 22 didn't comment, and so I can't answer.</p> <p>23 Q. Okay. That's outside the scope of this 24 report; is that fair?</p> <p>25 A. But I would be guessing just because I</p>

<p>1 don't have the information readily available.</p> <p>2 Q. That's a little different. One is if you</p> <p>3 want the information, you can look at it in your</p> <p>4 report; but if you are not opining on it at this</p> <p>5 time, then you have no opinion at this time, sir.</p> <p>6 So which is it?</p> <p>7 A. I think the way you said it second. I</p> <p>8 have no opinion at this time is a good way to state</p> <p>9 it.</p> <p>10 Q. Very well, sir. We don't need to belabor</p> <p>11 it. Thank you.</p> <p>12 Now, is it appropriate for a drug</p> <p>13 manufacturer to not test its drug for nitrosamines</p> <p>14 after being asked to do so by regulators?</p> <p>15 MS. LOCKARD: Objection. That's a</p> <p>16 liability question, and it's outside the scope of</p> <p>17 his class-certification report. Also incomplete</p> <p>18 hypothetical, vague.</p> <p>19 THE WITNESS: Do I answer?</p> <p>20 MS. LOCKARD: If you are able to.</p> <p>21 THE WITNESS: You know, I would generally</p> <p>22 say the answer to your question is no, it's not</p> <p>23 appropriate.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Are you aware of whether Teva ever tested</p>	<p>Page 170</p> <p>1 need to have reason to believe you may need to test</p> <p>2 your product for NDEA?</p> <p>3 A. Well, I think in the particular example,</p> <p>4 Mylan was saying they had reason to believe that</p> <p>5 there was no possibility of NDEA being in their drug</p> <p>6 substance.</p> <p>7 Q. Uh-huh.</p> <p>8 A. And Teva could look at the other</p> <p>9 ingredients in the manufacturing process and</p> <p>10 conclude that there was no reason to test --</p> <p>11 Q. Uh-huh.</p> <p>12 A. -- and that it could be in the market.</p> <p>13 And I think that's what this memo speaks to.</p> <p>14 Q. Okay. Did Teva, to your knowledge, in</p> <p>15 fact, look at the Mylan manufacturing process to</p> <p>16 determine whether or not NDEA could arise?</p> <p>17 MS. LOCKARD: Objection. Vague. Outside</p> <p>18 the scope.</p> <p>19 THE WITNESS: I can't say I can speak to</p> <p>20 that, Mr. Stanoch. My belief is they did. They</p> <p>21 were working with Mylan to get the needed</p> <p>22 information. But I don't have specific documents to</p> <p>23 support that view.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Uh-huh. If we go back to the exhibit we</p>
<p>Page 171</p> <p>1 its valsartan product for any nitrosamines after</p> <p>2 receiving a request from any regulator to do so?</p> <p>3 A. Well, I know they did test their</p> <p>4 nitrosamine -- I'm sorry, their valsartan-containing</p> <p>5 drug products at FDA's request, and they provided</p> <p>6 FDA with that information.</p> <p>7 Q. And that was for NDMA, those tests, I</p> <p>8 think, right?</p> <p>9 A. I agree, it was for NDMA, and I can't say</p> <p>10 whether it was for NDEA.</p> <p>11 Q. Okay. If a finished-dose customer asked</p> <p>12 Teva, do your products contain NDEA, would it be</p> <p>13 appropriate for Teva to conduct that testing and see</p> <p>14 if NDEA is in the products?</p> <p>15 MS. LOCKARD: Objection. Confusing.</p> <p>16 Vague.</p> <p>17 THE WITNESS: Well, I would say if Teva</p> <p>18 had reason to believe that there was no NDEA in</p> <p>19 their valsartan products, Teva would refuse. I</p> <p>20 mean, it might be a very big deal to do that kind of</p> <p>21 testing.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Uh-huh.</p> <p>24 A. So I would say it's not appropriate.</p> <p>25 Q. Uh-huh. And what information would you</p>	<p>Page 173</p> <p>1 were looking at a moment ago, the lift hold status</p> <p>2 memo; do you have that still, sir?</p> <p>3 A. Yes, I'm looking at it. July 6, 2018?</p> <p>4 Q. Uh-huh. Right. And it states that,</p> <p>5 "Mylan confirmed via e-mail to not have received any</p> <p>6 intermediates from Huahai." Do you see that?</p> <p>7 A. I do see that.</p> <p>8 Q. And further, so that -- strike that.</p> <p>9 So that was one basis for Teva's lifting</p> <p>10 the hold of the Mylan API product, right?</p> <p>11 A. Yes. And you can see in the last bullet</p> <p>12 on the thing where Teva's concluding possibility for</p> <p>13 NDMA impurity is negligible. I don't think the</p> <p>14 focus was on NDEA just yet.</p> <p>15 Q. Uh-huh. Right. At the time Teva lifted</p> <p>16 its hold, it wasn't even discussing, at least in</p> <p>17 this memo, anything about NDEA, right?</p> <p>18 A. Right. And I think that was the case for</p> <p>19 FDA. The concern about NDEA came later, after NDMA.</p> <p>20 Q. Uh-huh. And what is your understanding of</p> <p>21 the route of how nitrosamines came to be in Mylan's</p> <p>22 valsartan API?</p> <p>23 A. I have seen a description of it, and I</p> <p>24 think I have even seen statements from Mylan saying</p> <p>25 that the process was such that nitrosamines couldn't</p>

<p>1 be formed. But beyond that, I don't have any 2 specific information now.</p> <p>3 Q. I mean, do you understand that it was an 4 issue relating to the residual solvents that Mylan 5 was using in the valsartan API manufacturing 6 process?</p> <p>7 A. Yes, I do understand that, and that 8 relates to FDA's inspection of Lantech and a warning 9 letter to Lantech about failure to look for the 10 nitrosamine impurity.</p> <p>11 Q. You are aware that Lantech was the vendor 12 that was managing the solvent recovery process for 13 Mylan when Mylan was making valsartan API for Teva, 14 right?</p> <p>15 A. Yes, I am aware of that.</p> <p>16 Q. Uh-huh. And you understand that Lantech 17 was faulted by the FDA for the manner in which it 18 managed the solvent recovery process for Mylan, 19 right?</p> <p>20 A. Yes, I had that general understanding.</p> <p>21 Q. And that was the root cause for the NDEA 22 contamination of Mylan's valsartan API, right?</p> <p>23 A. That's my understanding as well.</p> <p>24 Q. Did Teva know that Mylan was using a 25 solvent-recovery vendor in the manufacture of</p>	<p>Page 174</p> <p>1 not its API supplier was using recycled solvents in 2 the valsartan API manufacturing process?</p> <p>3 MS. LOCKARD: Objection. Lacks 4 foundation. Outside the scope of his report.</p> <p>5 THE WITNESS: You know, well, one of the 6 ways I might answer that question is that the DMF 7 system might preclude Teva from knowing because the 8 processes of the DMF may be secret between Mylan and 9 Teva.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Well, do you see anything suggesting that 12 Teva ever asked Mylan about whether it was using 13 recycled solvents?</p> <p>14 A. I don't recall seeing any information to 15 that point.</p> <p>16 Q. Do you recall looking at anything 17 suggesting that Teva ever asked to see Mylan's DMF 18 for valsartan API?</p> <p>19 MS. LOCKARD: Objection. Asked and 20 answered. It's outside the scope.</p> <p>21 THE WITNESS: No, it wasn't a focus of my 22 report, and I don't recall seeing it.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Do you agree that the "Residual Solvents" 25 chapter of the USP would be part of the chapters and</p>
<p>Page 175</p> <p>1 valsartan API?</p> <p>2 A. I don't know that. I couldn't answer that 3 question.</p> <p>4 Q. All right. Sitting here today, can you 5 recall anything you saw suggesting that Teva ever 6 asked Mylan if Mylan was using a vendor for the 7 solvent recovery process in the manufacture of 8 valsartan API?</p> <p>9 A. I can't answer that. I don't have that 10 information.</p> <p>11 Q. Uh-huh. Did Teva know that Mylan was 12 using recycled solvents at all in the manufacture of 13 valsartan API?</p> <p>14 A. I can't say what Teva knew or didn't know.</p> <p>15 Q. Sitting here today, can you tell me 16 anything you saw suggesting, even, that Teva knew 17 that Mylan was using recycled solvents in the 18 manufacture of valsartan API?</p> <p>19 A. I think there is information about it, but 20 I don't have it and I can't comment.</p> <p>21 Q. Uh-huh. Right. You can't elaborate any 22 more on that, can you?</p> <p>23 A. No.</p> <p>24 Q. Right. Shouldn't Teva, as the 25 finished-dose manufacturer, understand whether or</p>	<p>Page 177</p> <p>1 notices which manufacturers should take into account 2 when they are manufacturing their own finished-dose 3 valsartan?</p> <p>4 MS. LOCKARD: Objection. Vague.</p> <p>5 THE WITNESS: I think "Residual Solvents" 6 is an ICH document that is important to 7 manufacturers as a recommendation, so I think I 8 would answer that yes.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Uh-huh. Do you know whether Teva adhered 11 to the USP "Residual Solvents" Chapter 467 in 12 assessing the valsartan API it purchased from Mylan?</p> <p>13 A. I think my understanding would be that in 14 the certificate of analysis for valsartan, there may 15 be a test for residual solvents. And we could 16 certainly look at that.</p> <p>17 Q. Well, you looked at a number of 18 certificates, I believe, listed in your materials 19 considered, right?</p> <p>20 A. No. That doesn't mean I looked at them. 21 They are listed in my materials considered, but they 22 weren't important to my report and I didn't cite 23 them.</p> <p>24 Q. Fair enough. Can you say sitting here 25 today whether you saw any mention of the use of</p>

<p>1 recycled solvents by Mylan in the manufacture of 2 valsartan API? 3 A. No, I didn't see anything about recycled 4 solvents. 5 Q. And a moment ago you were talking about 6 the potential confidentiality of DMFs. Do you 7 remember that? 8 A. I do. 9 Q. Is the mere existence of a third-party 10 vendor secret? 11 MS. LOCKARD: Objection. Foundation. 12 Speculation. 13 THE WITNESS: I don't quite understand. 14 Secret from whom? 15 BY MR. STANOCH: 16 Q. Does the fact that Mylan was using a 17 third-party vendor, Lantech, to manage the solvent 18 recovery process for valsartan API -- strike that. 19 You were suggesting, were you not, that 20 some of Mylan's DMF might have been confidential and 21 not shareable with Teva, right? 22 A. Right, right. 23 Q. Right. So is it your position, sir, that 24 the mere fact that Mylan was using a third-party 25 vendor at all for the solvent recovery process was</p>	<p>Page 178</p> <p>1 These are sellers of a drug substance that Teva 2 purchased. 3 BY MR. STANOCH: 4 Q. Uh-huh. So it's your position that -- oh, 5 strike that. 6 Would it surprise you to know that Mylan 7 was contracting with a third-party vendor in India 8 who had never been inspected by the FDA? 9 A. No, it wouldn't surprise me. 10 Q. And do you think Teva would have any issue 11 if it learned that Mylan was contracting with a 12 third-party vendor in India who had never been 13 inspected by the FDA? 14 MS. LOCKARD: Objection -- 15 MR. STOY: Frank Stoy for Mylan. I am 16 just going to object to the form of the question. 17 (Reporter clarification.) 18 MR. STOY: Yes, I just stated an objection 19 to the form of the question. Thank you. 20 MS. LOCKARD: I objected as well as vague. 21 And calls for speculation. 22 THE WITNESS: But I feel like I'm losing 23 Mr. Stanoch. 24 BY MR. STANOCH: 25 Q. Can you hear me, sir?</p> <p>Page 180</p>
<p>1 something that would be confidential and not 2 shareable with Teva? 3 A. Well, it could be. I just don't know what 4 Mylan wanted to keep confidential in the DMF. 5 Q. Uh-huh. And if -- oh. 6 A. And again, remember, typically what you 7 see in the DMF for the purchaser, in this case, 8 Teva, is the certificate of analysis, the 9 specification for the drug substance. 10 Q. And again, those certificates and 11 analysis, to the extent you recall sitting here 12 today, made no mention of the use of recycled 13 solvents? 14 A. It may have a specification for residual 15 solvents. We would have to look at one to see. But 16 I don't think that necessarily would tell anything 17 about whether the solvents were recycled or not. 18 Q. Uh-huh. And one way Teva could have had 19 additional information about Lantech would be if it 20 had a quality agreement in place with Mylan, 21 correct? 22 MS. LOCKARD: Objection. Speculation. 23 THE WITNESS: You know, quality agreements 24 may relate to contract manufacturers, but for both 25 ZHP and Mylan, these are not contract manufacturers.</p>	<p>Page 179</p> <p>1 A. Yeah, now I can hear you clearly. 2 Q. I will repeat the -- 3 A. Can you repeat -- 4 Q. I would love to because of the 5 interference -- I don't mean that pejoratively -- 6 from defense counsel. 7 Sir, do you think Teva would have an issue 8 if it learned that Mylan was using a third-party 9 vendor in India who had never been inspected by the 10 FDA to manage the solvent recovery process? 11 MS. LOCKARD: Same objection. 12 THE WITNESS: I can't really speculate 13 what Teva would think about it. It doesn't seem to 14 me a big issue whether there is or is not an FDA 15 inspection. 16 BY MR. STANOCH: 17 Q. It's not a big issue if Teva was buying 18 valsartan API from Mylan where Mylan was using a 19 third-party vendor not disclosed to Teva who had 20 never been inspected by the FDA; is that your 21 testimony? 22 A. I'm not really an expert on solvent 23 recovery processes, but my understanding is that 24 many companies use them. It's not unusual. And to 25 me it might be part of the DMF that Mylan would want</p> <p>Page 181</p>

<p>1 to keep confidential.</p> <p>2 And then the issue of an FDA inspection</p> <p>3 is -- to tell you the truth, Mr. Stanoch, when I saw</p> <p>4 that FDA had inspected Lantech, this was the first</p> <p>5 time I had ever heard of FDA inspecting a</p> <p>6 solvent-recovery manufacturer.</p> <p>7 Q. Uh-huh. And that happened after news of</p> <p>8 the nitrosamines broke in 2018, though, right?</p> <p>9 A. Yes, that's when the inspection occurred</p> <p>10 for Lantech.</p> <p>11 Q. Right. And Teva never inspected Lantech</p> <p>12 prior to 2018, did it?</p> <p>13 A. I don't know that.</p> <p>14 Q. Right. And did you see anything in any of</p> <p>15 the documents you reviewed suggesting that Teva ever</p> <p>16 inspected Lantech prior to 2018?</p> <p>17 A. No, I didn't see anything like that.</p> <p>18 Q. And you never saw anything even suggesting</p> <p>19 Teva knew who Lantech was prior to 2018, correct?</p> <p>20 A. I never saw anything to that point.</p> <p>21 Q. Would it surprise you to know that Mylan</p> <p>22 was also using Lantech to do second-crop harvesting</p> <p>23 of valsartan API?</p> <p>24 MS. LOCKARD: Objection. Foundation.</p> <p>25 Speculation. Outside the scope of his report.</p>	<p>1 support an answer.</p> <p>2 BY MR. STANOCHE:</p> <p>3 Q. Okay. Wouldn't a contract between Mylan</p> <p>4 and Teva allow those two firms to exchange</p> <p>5 confidential information?</p> <p>6 MS. LOCKARD: Objection. Speculation.</p> <p>7 Outside the scope.</p> <p>8 THE WITNESS: I could imagine a contract</p> <p>9 that would support that kind of exchange of</p> <p>10 information.</p> <p>11 BY MR. STANOCHE:</p> <p>12 Q. Right.</p> <p>13 A. But it can occur without a contract.</p> <p>14 Q. It certainly could, but that exchange did</p> <p>15 not occur here between Teva and Mylan about the</p> <p>16 recycled solvents and Lantech, did it?</p> <p>17 A. I just have no information to that point,</p> <p>18 but if that's what you say, I certainly wouldn't</p> <p>19 debate you.</p> <p>20 Q. And you would agree, though, that Teva</p> <p>21 could have contractually required Mylan to disclose</p> <p>22 information about the solvent recovery process,</p> <p>23 correct?</p> <p>24 MS. LOCKARD: Objection. Speculation.</p> <p>25 Outside the scope.</p>
<p>1 THE WITNESS: I don't understand the</p> <p>2 question and I have no information to answer it.</p> <p>3 BY MR. STANOCHE:</p> <p>4 Q. Uh-huh. Teva could not make its</p> <p>5 assessment about the recycled-solvent process</p> <p>6 without knowing anything about it, correct?</p> <p>7 MS. LOCKARD: Objection. Vague.</p> <p>8 THE WITNESS: That seems like a generally</p> <p>9 true statement, so I can agree.</p> <p>10 BY MR. STANOCHE:</p> <p>11 Q. Uh-huh. And absent a contractual</p> <p>12 arrangement that would obligate Mylan to disclose</p> <p>13 that information, Mylan didn't have to disclose it</p> <p>14 to Teva; is that your statement?</p> <p>15 A. No, I'm not making that statement.</p> <p>16 Q. Uh-huh. If there was a contract between</p> <p>17 Mylan and Teva that governed disclosure of the</p> <p>18 processes and entities involved in the valsartan API</p> <p>19 manufacturing process, Teva could have learned about</p> <p>20 Lantech prior to all the recalls in 2018, right?</p> <p>21 MS. LOCKARD: Objection. Speculation.</p> <p>22 Foundation. Outside the scope of his</p> <p>23 class-certification opinions.</p> <p>24 THE WITNESS: Yeah, I would have to</p> <p>25 speculate on that. I just have no information to</p>	<p>1 THE WITNESS: Yeah, again, everything you</p> <p>2 are asking me, I would be required to speculate</p> <p>3 because I just don't have the information.</p> <p>4 BY MR. STANOCHE:</p> <p>5 Q. Do you know whether Teva ever performed a</p> <p>6 residual solvent analysis with respect to Mylan</p> <p>7 valsartan API?</p> <p>8 A. I do not.</p> <p>9 Q. Do you know whether Mylan itself ever</p> <p>10 conducted a residual solvent analysis for the</p> <p>11 valsartan API it made?</p> <p>12 A. I do not know that.</p> <p>13 Q. Uh-huh. Did Teva ever ask to audit</p> <p>14 Lantech?</p> <p>15 A. Not that I'm aware of.</p> <p>16 Q. Right. Teva didn't even know who Lantech</p> <p>17 was, right?</p> <p>18 A. I don't know that.</p> <p>19 Q. Do you have any information suggesting</p> <p>20 that Teva knew about Lantech and its role in the</p> <p>21 Mylan valsartan API manufacturing process prior to</p> <p>22 the recalls?</p> <p>23 MS. LOCKARD: Objection. Speculation.</p> <p>24 Foundation. Outside the scope.</p> <p>25 THE WITNESS: I just don't know, and it</p>

<p>1 wasn't pertinent to my report.</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. Uh-huh. Are you aware of any evidence</p> <p>4 that Teva ever reviewed ZHP's route of synthesis for</p> <p>5 valsartan API prior to the 2018 recalls?</p> <p>6 MS. LOCKARD: Outside the scope.</p> <p>7 Objection.</p> <p>8 THE WITNESS: Well, I think if we look at</p> <p>9 the Watson CBE-30s -- Watson, of course, is a</p> <p>10 predecessor company to Teva -- there was information</p> <p>11 about the route of synthesis and the synthesis</p> <p>12 change.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. You are talking about the ZHP process</p> <p>15 change, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Right. And regarding that, ZHP was</p> <p>18 changing its manufacturing process for valsartan API</p> <p>19 that it was selling to, at the time, Actavis,</p> <p>20 correct?</p> <p>21 A. I would say Watson, but they were all</p> <p>22 predecessor companies to Teva.</p> <p>23 Q. That's fine. We can agree that Watson was</p> <p>24 a predecessor to Actavis and then Actavis was a</p> <p>25 predecessor to current Teva, right?</p>	<p>Page 186</p> <p>1 Q. So the fact that Watson characterized the</p> <p>2 ZHP process change as minor to moderate meant that</p> <p>3 it could implement its change immediately if it</p> <p>4 wanted, correct?</p> <p>5 A. Well, I would say the letter was the</p> <p>6 CBE-30, so they would wait to hear from FDA and then</p> <p>7 they could implement after 30 days.</p> <p>8 Q. Uh-huh. And in that context of that</p> <p>9 submission, did Watson, to your knowledge, review</p> <p>10 ZHP's entire DMF?</p> <p>11 A. As far as I know, they did not.</p> <p>12 Q. All right. Did Watson, Actavis, or Teva,</p> <p>13 to your knowledge, ever ask ZHP for a copy of ZHP's</p> <p>14 DMF for valsartan API?</p> <p>15 A. As far as I know, they did not.</p> <p>16 Q. Nothing stopped any of them from</p> <p>17 requesting that, correct?</p> <p>18 A. Well, I think it would be counter to the</p> <p>19 way a DMF works, that it's a separate filing to the</p> <p>20 agency. So I would say Teva would not ask for it.</p> <p>21 Q. Well, that wasn't quite my question, sir.</p> <p>22 The question was that nothing stopped Teva or its</p> <p>23 predecessor entities from asking ZHP for a copy of</p> <p>24 the DMF for valsartan API, correct?</p> <p>25 A. I think you are correct. I mean, the two</p>
<p>Page 187</p> <p>1 A. Yes, that sounds right.</p> <p>2 Q. Great. So we can use -- we can understand</p> <p>3 that as we go through. So ZHP changed it</p> <p>4 manufacturing process for the valsartan API it was</p> <p>5 selling to Watson, right?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. And ZHP characterized that as a minor to</p> <p>8 moderate change, correct?</p> <p>9 A. I would have to see the letters from</p> <p>10 Watson to FDA, but I think you are correct.</p> <p>11 Q. And a minor to moderate process change</p> <p>12 does not require preapproval from the FDA, does it?</p> <p>13 A. Well, I couldn't agree with that, because</p> <p>14 Watson was asking for FDA approval, but they</p> <p>15 submitted it as a CBE-30.</p> <p>16 Q. Right. And a CBE-30, Change Being</p> <p>17 Effected, does not technically require preapproval</p> <p>18 by the FDA, correct?</p> <p>19 A. The way I would say it is FDA will always</p> <p>20 come in and review it, but the change can be</p> <p>21 implemented if FDA doesn't respond within 30 days.</p> <p>22 Q. Right. A major process change requires a</p> <p>23 different level of review by the FDA, correct?</p> <p>24 A. That would be called the postapproval</p> <p>25 supplement.</p>	<p>Page 189</p> <p>1 companies could agree to completely share the</p> <p>2 contents of the DMF.</p> <p>3 Q. Right.</p> <p>4 A. But typically a DMF is not shared with the</p> <p>5 purchaser, such as Teva.</p> <p>6 Q. Uh-huh. And the DMF was not shared in</p> <p>7 this instance, as far as you know, with Teva or its</p> <p>8 predecessor entities?</p> <p>9 MS. LOCKARD: Objection. Asked and</p> <p>10 answered.</p> <p>11 THE WITNESS: I have to say I just don't</p> <p>12 know. If I had to guess, I would say not.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Uh-huh. To your knowledge, did Teva ever</p> <p>15 ask ZHP to confirm that ZHP's valsartan API did not</p> <p>16 contain any genotoxic substances?</p> <p>17 A. As far as I know, it was not an issue or a</p> <p>18 basis for communication until the summer of 2018.</p> <p>19 Q. Nothing's prevented Teva from ever asking</p> <p>20 ZHP to confirm that ZHP's valsartan API did not</p> <p>21 contain any genotoxic substances, correct?</p> <p>22 A. Are you saying nothing prevented them?</p> <p>23 Q. Yes. I'll restate it. Nothing prevented</p> <p>24 Teva from ever asking ZHP to confirm that ZHP's</p> <p>25 valsartan API did not contain any genotoxic</p>

<p>1 substances, correct?</p> <p>2 A. Well, if it was expected, I suppose Teva</p> <p>3 could certainly have asked, but it was unexpected.</p> <p>4 Q. Well, it was unexpected because ZHP said</p> <p>5 so; isn't that right?</p> <p>6 MS. LOCKARD: Objection to form.</p> <p>7 THE WITNESS: No, the reason I say it was</p> <p>8 unexpected, because FDA said so.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Well, FDA said it's unexpected because</p> <p>11 that's how ZHP characterized it originally when it</p> <p>12 was forced to break all this news in June 2018;</p> <p>13 isn't that right?</p> <p>14 MS. LOCKARD: Objection to form.</p> <p>15 MS. HILL: Objection. Argument.</p> <p>16 THE WITNESS: I just don't know that,</p> <p>17 Mr. Stanoch. If you know that, it's news to me.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Uh-huh. Uh-huh. Do you have any</p> <p>20 information as to where FDA may have gotten the term</p> <p>21 "unexpected" as to the nitrosamines found in</p> <p>22 valsartan products?</p> <p>23 A. I don't.</p> <p>24 Q. And would it surprise you if it came</p> <p>25 originally from ZHP?</p>	<p>Page 190</p> <p>1 API from ZHP?</p> <p>2 A. I think now they have resolved their</p> <p>3 issues with FDA, as I understand it, that arose and</p> <p>4 were summarized in the warning letter, and</p> <p>5 everything is fine between FDA and the company.</p> <p>6 Q. Uh-huh. So you would?</p> <p>7 A. Yes.</p> <p>8 Q. Uh-huh. How about before 2018?</p> <p>9 MS. LOCKARD: Objection. Vague.</p> <p>10 THE WITNESS: Well, I would say yes. My</p> <p>11 understanding is they had good FDA inspections, and</p> <p>12 many companies get warning letters where things can</p> <p>13 be resolved, and that's what happened for ZHP.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Uh-huh. And it's important, then, to know</p> <p>16 if your API supplier is receiving any adverse</p> <p>17 inspections from the FDA, correct?</p> <p>18 A. That's a separate topic. And -- is that a</p> <p>19 question? I'm sorry.</p> <p>20 Q. It's important to know if your API</p> <p>21 supplier is receiving any adverse inspection</p> <p>22 findings from the FDA, correct?</p> <p>23 A. I think it could be important, yes.</p> <p>24 Q. Okay. Yes. And a reasonable</p> <p>25 pharmaceutical manufacturer would want to know if</p>
<p>Page 191</p> <p>1 MS. LOCKARD: Objection. Speculation.</p> <p>2 Foundation.</p> <p>3 THE WITNESS: Yeah, I just can't answer.</p> <p>4 I don't know where it came from.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Uh-huh. If ZHP told the world this</p> <p>7 nitrosamine impurity was unexpected, but it had</p> <p>8 information suggesting it knew a year earlier, would</p> <p>9 that be important?</p> <p>10 MS. LOCKARD: Objection to form.</p> <p>11 THE WITNESS: I just have to speculate. I</p> <p>12 don't know when ZHP had its information. It seemed</p> <p>13 to me it was closer to the summer of 2018 time</p> <p>14 frame.</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Uh-huh. Did you evaluate whether ZHP had</p> <p>17 any information suggesting there may be nitrosamines</p> <p>18 in its valsartan API prior to June 2018?</p> <p>19 A. I did not see any information to that</p> <p>20 point.</p> <p>21 Q. Was that even part of your analysis for</p> <p>22 purposes of your class-certification report?</p> <p>23 A. No.</p> <p>24 Q. Uh-huh. In the context of your consulting</p> <p>25 work, sir, would you advise a company to purchase</p>	<p>Page 193</p> <p>1 its API supplier is receiving adverse inspections</p> <p>2 and findings from the FDA, correct?</p> <p>3 MS. LOCKARD: Objection. Outside the</p> <p>4 scope. That's clearly a liability question.</p> <p>5 THE WITNESS: And I -- you know, there are</p> <p>6 so many variables underlying your question. I mean,</p> <p>7 FDA may inspect and make a few observations that are</p> <p>8 quickly resolved. I'm not sure that needs to be</p> <p>9 communicated to buyers.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Uh-huh. If a manufacturer of</p> <p>12 finished-dose product learns about an FDA inspection</p> <p>13 and requests information about it from its API</p> <p>14 supplier, would it be your expectation that the API</p> <p>15 supplier would provide the information?</p> <p>16 MS. LOCKARD: Objection. Speculation.</p> <p>17 Foundation. Incomplete hypothetical.</p> <p>18 THE WITNESS: Yes, and I just don't have</p> <p>19 any basis to have an answer to that question.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Well, you consult pharmaceutical</p> <p>22 manufacturers, don't you, sir?</p> <p>23 A. I would say now I am doing primarily</p> <p>24 litigation, and I have never consulted on the type</p> <p>25 of questions you are raising now.</p>

<p>1 Q. Right, uh-huh. Have you ever advised a 2 company that it's prudent for them to have all 3 available information about regulatory inspections 4 of their API supplier?</p> <p>5 A. I have not.</p> <p>6 Q. Uh-huh. Are there ways for pharmaceutical 7 manufacturers to independently check on whether 8 their API suppliers have had adverse regulatory 9 findings?</p> <p>10 A. Well, certainly a warning letter is 11 public, so that could come to light independent of a 12 drug-substance manufacturer.</p> <p>13 Q. Uh-huh. Are you aware of any processes 14 Teva had in place prior to June 2018 to monitor 15 whether its API suppliers were receiving adverse 16 findings from regulators?</p> <p>17 A. I am not.</p> <p>18 Q. Uh-huh. And back to ZHP and Teva. To 19 your knowledge, Teva never asked ZHP to confirm that 20 ZHP's valsartan API did not contain any genotoxic 21 substances, correct?</p> <p>22 MS. LOCKARD: Objection. Asked and 23 answered.</p> <p>24 THE WITNESS: Yes, I am not aware of any 25 communication like that.</p>	<p>Page 194</p> <p>1 MR. STANOCH: Counsel, I'm not debating 2 you now on the record. I'm going to keep asking my 3 questions. You are lodging your objections. I'm 4 asking questions on the facts on which he is opining 5 about. It's within the scope of his report.</p> <p>6 He says a number of factual --</p> <p>7 MS. LOCKARD: I just want to --</p> <p>8 MR. STANOCH: Excuse me. He makes a 9 number of statements about facts. I'm entitled to 10 probe the facts as they relate to the opinions in 11 this report.</p> <p>12 MS. LOCKARD: You are not asking about 13 facts, though. You are asking about his opinion as 14 to whether something is reasonable, prudent, 15 appropriate, and those are the questions that I'm 16 objecting to. Now, I understand --</p> <p>17 MR. STANOCH: You have stated your 18 objections.</p> <p>19 MS. LOCKARD: -- you are going to keep 20 asking, but we're going to move to strike all this 21 testimony and you are not going to be able to come 22 back and ask him or anyone else these questions.</p> <p>23 MR. STANOCH: Well, I disagree with that. 24 I'm asking him questions relating to the facts and 25 the opinions in this report. And we will keep</p>
<p>Page 195</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Uh-huh. Wouldn't it have been prudent for 3 Teva to request such a statement from ZHP regarding 4 the valsartan API?</p> <p>5 MS. LOCKARD: Objection. Outside the 6 scope of his report. It's liability opinion.</p> <p>7 You are just -- I'm sorry, Mr. Stanoch, 8 but you have just completely disregarded any sort of 9 line, bright or not, between liability opinion and 10 his class-certification opinion. I'm honestly at a 11 loss as to whether we need to suspend and call a 12 judge or meet and confer on this.</p> <p>13 But, I mean, I hate to just keep objecting 14 to every question, but every question is, you know, 15 what would a prudent manufacturer do? What would be 16 reasonable? You know, what should they do? Would 17 it be appropriate? These are all liability 18 opinions.</p> <p>19 MR. STANOCH: Are you done, Counsel?</p> <p>20 MS. LOCKARD: No, because I'm having a 21 problem here.</p> <p>22 MR. STANOCH: Are you done, Counsel?</p> <p>23 MS. LOCKARD: No. Do you want to go off 24 the record or you want to discuss it on the record?</p> <p>25 What is your response?</p>	<p>Page 197</p> <p>1 going.</p> <p>2 MS. LOCKARD: Well, this will be taken up 3 with Judge Vanaskie, so --</p> <p>4 MR. STANOCH: I don't appreciate the 5 threat, Counsel.</p> <p>6 MS. LOCKARD: It is not a threat -- a 7 statement. But go ahead.</p> <p>8 MR. STANOCH: For the record, Counsel, 9 I'll state that in his own report, Dr. Williams 10 opines on reasonableness a number of times in terms 11 of methods, in terms of what one would do, in terms 12 of risk assessments, et cetera, so it's in the 13 report. We can look at it later.</p> <p>14 Q. So, Doctor --</p> <p>15 MS. LOCKARD: I disagree with your 16 assessment.</p> <p>17 (Reporter clarification.)</p> <p>18 MS. LOCKARD: I said I disagree with the 19 assessment, but go ahead.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Uh-huh. Dr. Williams, you state in 22 Paragraph 84 of your report that there is no issue 23 with the FDA inspection of ZHP in 2017 because an 24 EIR was provided; is that right?</p> <p>25 A. Wait a minute, if I could get to where you</p>

<p>1 are now. Which paragraph?</p> <p>2 Q. 84.</p> <p>3 A. And what page? Yeah.</p> <p>4 Q. I don't have a printed copy of the report</p> <p>5 you produced this morning, so I can't tell you the</p> <p>6 exact page, sir. Sorry. It's Paragraph 84.</p> <p>7 A. Page 28. Yes. And, of course, others</p> <p>8 will comment on ZHP's inspectional history, but this</p> <p>9 is an example of an inspection that ZHP got in 2017,</p> <p>10 an FDA 483 with a small number of observations, and</p> <p>11 as FDA does, they provided an EIR, indicating that</p> <p>12 the inspection was closed.</p> <p>13 Q. Are you suggesting here that because the</p> <p>14 FDA did not continue the inspection, there were no</p> <p>15 problems with ZHP's valsartan API?</p> <p>16 A. Well, that's a difficult question to give</p> <p>17 a conjecture about. What I would say is I can't say</p> <p>18 more than what the facts state, that ZHP responded</p> <p>19 to the observations, FDA found them satisfactory and</p> <p>20 issued an EIR.</p> <p>21 Q. Was Teva ever made aware of the FDA</p> <p>22 inspection of ZHP's facility in 2017? Did it learn</p> <p>23 of that in the year 2017?</p> <p>24 A. I don't know that.</p> <p>25 Q. Right. Do you know when, if at all, Teva</p>	<p>Page 198</p> <p>1 was reviewing the DMF and was certainly likely to</p> <p>2 imagine that FDA would inspect ZHP, so it would be</p> <p>3 hard to imagine that Teva didn't have some</p> <p>4 understanding of those possibilities. But in terms</p> <p>5 of the discrete facts of those possibilities, I have</p> <p>6 no information.</p> <p>7 Q. Uh-huh. Is there only a potential cGMP</p> <p>8 problem with an API supplier if the FDA catches it</p> <p>9 first?</p> <p>10 A. No. I don't think that is a fair</p> <p>11 statement. I would say the essence of GMPs is the</p> <p>12 manufacturer is supposed to create their own</p> <p>13 approach to GMPs that then is suitable for an FDA</p> <p>14 inspection, but the FDA inspection may occur</p> <p>15 infrequently.</p> <p>16 Q. Uh-huh. Right. It's incumbent on a</p> <p>17 manufacturer sourcing API to conduct its own due</p> <p>18 diligence of the API manufacturer, correct?</p> <p>19 A. Are you talking about the purchaser?</p> <p>20 Q. Yes. It's incumbent on the finished-dose</p> <p>21 manufacturer purchasing API to conduct its own due</p> <p>22 diligence of the API supplier, correct?</p> <p>23 A. I think that's a reasonable statement,</p> <p>24 yes.</p> <p>25 Q. Uh-huh. And further down in your report,</p>
<p>Page 199</p> <p>1 learned that FDA inspected ZHP's API facility in</p> <p>2 2017?</p> <p>3 A. I'm not aware of what FDA knew about ZHP</p> <p>4 inspectional history. Of course they knew about the</p> <p>5 warning letter because that was public.</p> <p>6 Q. Well, the warning letter was from 2018,</p> <p>7 after the recalls, right?</p> <p>8 A. Yes.</p> <p>9 Q. Right. So I'm asking -- a different</p> <p>10 question is: What is your understanding of when</p> <p>11 Teva knew about the FDA inspection of ZHP that</p> <p>12 occurred in 2017?</p> <p>13 A. I have no information about that.</p> <p>14 Q. Right. So you don't know one way or the</p> <p>15 other when Teva might have learned that the FDA</p> <p>16 inspected ZHP's API facility in 2017?</p> <p>17 A. Yes, I don't know that.</p> <p>18 Q. Do you know when if at all ZHP revealed</p> <p>19 the observations from the 2017 FDA inspection to</p> <p>20 Teva?</p> <p>21 A. I don't know that they revealed it to</p> <p>22 Teva.</p> <p>23 Q. Was Teva ever relying on the FDA to</p> <p>24 determine the acceptability of ZHP's valsartan API?</p> <p>25 A. Well, I think Teva would be aware that FDA</p>	<p>Page 201</p> <p>1 beginning Section F, do you see this? It's "FDA</p> <p>2 Inspections of Teva Drug Product Manufacturing</p> <p>3 Facilities"; do you see that, sir?</p> <p>4 A. I do.</p> <p>5 Q. Okay. And here you talk about FDA</p> <p>6 inspections of Teva's own finished-dose facilities</p> <p>7 that had been manufacturing valsartan prior to the</p> <p>8 recalls; is that fair?</p> <p>9 A. Yes, FDA inspections.</p> <p>10 Q. Right. And are you suggesting that just</p> <p>11 because the FDA didn't find a problem relating to</p> <p>12 valsartan, that there was no issue with the</p> <p>13 valsartan API that the Malta and Jerusalem</p> <p>14 facilities were sourcing from ZHP and Mylan?</p> <p>15 A. I don't know that. I couldn't comment.</p> <p>16 Q. And are you suggesting here that because</p> <p>17 the FDA did not find any adulteration during the</p> <p>18 inspections you list in your report here, that</p> <p>19 Teva's product could not be adulterated with</p> <p>20 nitrosamines during these same time periods?</p> <p>21 A. I'm saying that Teva in my report had</p> <p>22 recalled all its valsartan products from the market</p> <p>23 before FDA made any determinations related to</p> <p>24 adulteration.</p> <p>25 Q. Well, Teva's products had API with</p>

<p>1 nitrosamines in it prior to the recalls, right?</p> <p>2 A. Yes, I think that was the basis for the</p> <p>3 recall.</p> <p>4 Q. Right. So are you telling me that a</p> <p>5 valsartan product made by Teva the day before the</p> <p>6 recalls with nitrosamines is not adulterated, but</p> <p>7 then once the recall is issued the next day, now</p> <p>8 that product is adulterated?</p> <p>9 A. No, I'm saying the adulteration label, if</p> <p>10 somebody wanted to say, when did it occur, it</p> <p>11 occurred with the warning letters that went to ZHP</p> <p>12 and Mylan, and it also occurred after FDA set limits</p> <p>13 for the nitrosamine impurities in December 2018.</p> <p>14 But before that, Teva had recalled all product from</p> <p>15 the U.S. market.</p> <p>16 Q. Uh-huh.</p> <p>17 A. Both made in Jerusalem and Malta.</p> <p>18 Q. Uh-huh. Are you saying that valsartan</p> <p>19 sold by Teva prior to the FDA's issuance of warning</p> <p>20 letters to ZHP and Mylan could not be considered</p> <p>21 adulterated?</p> <p>22 A. Yes.</p> <p>23 Q. So a Teva valsartan product on a certain</p> <p>24 day that had nitrosamines in it is not adulterated</p> <p>25 until the FDA issues a warning letter to ZHP or</p>	<p>Page 202</p> <p>1 A. Yes, yes, go ahead.</p> <p>2 Q. Number two would be when FDA issued a</p> <p>3 warning letter to Mylan, right? Right?</p> <p>4 A. Yes, uh-huh.</p> <p>5 Q. Number three would be when FDA set interim</p> <p>6 limits, which you say occurred in December of 2018,</p> <p>7 correct?</p> <p>8 A. Yes, I think that's -- I'm looking at my</p> <p>9 report to see if those opinions are clearly stated.</p> <p>10 Let me check. But that corresponds to my opinion.</p> <p>11 Q. So let's say the FDA never set interim</p> <p>12 limits and let's say the FDA never issued warning</p> <p>13 letters to ZHP or Mylan. In that case, Teva's</p> <p>14 finished-dose valsartan could never be considered</p> <p>15 adulterated, according to you?</p> <p>16 A. Yes, I think the issue of adulteration</p> <p>17 arose and was determined, to the extent it was</p> <p>18 determined at all, after Teva had recalled all</p> <p>19 product from the market.</p> <p>20 Q. So then the answer is that Teva's</p> <p>21 valsartan products would never be considered</p> <p>22 adulterated in a world where the FDA did not issue</p> <p>23 warning letters to ZHP and Mylan and the FDA set no</p> <p>24 interim limits?</p> <p>25 A. Yeah, I don't think FDA -- yeah, if we</p>
<p>Page 203</p> <p>1 Mylan, and then once that happens, then it's</p> <p>2 adulterated?</p> <p>3 A. That's when a formal regulatory definition</p> <p>4 of adulteration could be stated to have occurred.</p> <p>5 And it could also have been stated to have occurred</p> <p>6 when FDA set limits for nitrosamine in December of</p> <p>7 2018.</p> <p>8 Q. So going back to our examples we had</p> <p>9 talked about before a couple breaks, if there is a</p> <p>10 product that is containing anthrax, it's not</p> <p>11 adulterated until the FDA issues a Form 483?</p> <p>12 A. No, no, no. I would say a 483 is not a</p> <p>13 FDA determination of adulteration. A regulatory</p> <p>14 determination of adulteration by FDA is a very</p> <p>15 serious matter and, you know, it's carefully</p> <p>16 considered by FDA, and I am suggesting that it could</p> <p>17 have been determined to have occurred on those three</p> <p>18 points that I just stated.</p> <p>19 But Teva had recalled all of its product</p> <p>20 before FDA made any kind of statement that could be</p> <p>21 deemed an interpretation of adulteration.</p> <p>22 Q. So it sounds like the only three points</p> <p>23 that you say adulteration could be found is when,</p> <p>24 number one, FDA issued a warning letter to ZHP,</p> <p>25 right?</p>	<p>Page 205</p> <p>1 say, was the Mylan product adulterated, I would say</p> <p>2 it couldn't -- FDA had not made a decision in that</p> <p>3 regard at least until those three prongs, if you</p> <p>4 will, had been met.</p> <p>5 Q. Say a warning letter finds a product</p> <p>6 adulterated on January 1, 2022. Does that mean that</p> <p>7 on December 31, 2021, that same product was not</p> <p>8 adulterated?</p> <p>9 A. Yeah, I think the issue of adulteration</p> <p>10 is -- and I'm looking at page 8 in my opinion, under</p> <p>11 B, and my opinion is clear. "My opinion that Teva's</p> <p>12 valsartan products were, at all times prior to</p> <p>13 Teva's voluntary recalls, AB-rated to their branded</p> <p>14 counterparts and were not adulterated or</p> <p>15 misbranded." That's what I'm saying.</p> <p>16 Now, if somebody wants to raise an issue</p> <p>17 of when adulteration occurred, I would say it was</p> <p>18 when the warning letters went to ZHP and Mylan or</p> <p>19 when FDA set limits on the nitrosamine impurities in</p> <p>20 December 2018. I think that's a very clear</p> <p>21 conclusion on my report.</p> <p>22 Q. Well, how does the FDA take action for</p> <p>23 adulterated product, then, for product that had</p> <p>24 already been sold if nothing is adulterated until</p> <p>25 they issue a warning letter?</p>

<p>1 A. FDA can ask for recalls of products that 2 are objectionable for various reasons. You 3 mentioned examples yourself. But it doesn't mean 4 that FDA is making an adulteration charge. That's a 5 separate issue.</p> <p>6 Q. So according to you, adulteration can only 7 exist if the FDA issues a warning letter?</p> <p>8 A. I would say an adulteration charge is a 9 regulatory determination by FDA that is very 10 carefully considered. Even a warning letter doesn't 11 necessarily mean, you know, an adulteration charge. 12 It's really a signal to a company that they need to 13 focus a little bit more on improving their GMPs.</p> <p>14 All I'm saying is that Teva products were 15 not adulterated at the time of the recall, so Teva 16 never had adulterated product in the U.S. market.</p> <p>17 Q. Because you are saying the warning letters 18 were not issued to ZHP or Mylan until after Teva's 19 recalls?</p> <p>20 A. Yes. If somebody wants to make an 21 adulteration claim here, it seems to me it would 22 occur then, or when FDA set limits and a product was 23 above those limits. The FDA -- oh.</p> <p>24 Q. So all the --</p> <p>25 A. FDA could have set limits that would have</p>	<p>1 you cite in your report, sir.</p> <p>2 A. Is it? I don't recall FDA making an 3 adulteration claim in the 483s. Can you show me 4 that?</p> <p>5 Q. In the warning letters, I apologize. In 6 the warning letters the FDA said that Mylan and 7 ZHP's API was adulterated, correct?</p> <p>8 A. Yes. I mean, you are reiterating my 9 claim. That's a point at which FDA could be said to 10 have determined a charge of adulteration.</p> <p>11 Q. Uh-huh. So --</p> <p>12 A. And that is a very carefully considered 13 charge.</p> <p>14 Q. All right. So if I am selling a product 15 starting today, and it contains rat poison, I can 16 keep selling that and keep selling it until the FDA 17 issues me a warning letter, correct?</p> <p>18 A. No. I think your hypothetical, it needs 19 to be refined for this particular case. There is an 20 impurity, an impurity that we have already talked 21 about is undesirable. It's part of that cohort of 22 concern.</p> <p>23 But it can have a limit set on it such 24 that the product is safe and effective and of good 25 quality. FDA did not do that until December 2018.</p>
<p>1 let the Teva product be okay. It was just an 2 uncertainty there. But because FDA thought the 3 limits were unacceptably high, without a limit being 4 set, Teva and FDA agreed that these products should 5 come off the market, first ZHP-containing product 6 and then the Mylan product.</p> <p>7 Q. Uh-huh.</p> <p>8 A. And then Teva decided not to reenter the 9 market at all.</p> <p>10 So Teva never had an adulterated product 11 for any of its four valsartan-containing products in 12 the U.S. market.</p> <p>13 Q. Uh-huh. So from 2012 on, assume all of 14 Teva's products had nitrosamines in it leading up to 15 the recall. You are saying all of that product 16 cannot be considered adulterated?</p> <p>17 A. It was not adulterated --</p> <p>18 Q. Uh-huh.</p> <p>19 A. -- according to an FDA regulatory 20 determination.</p> <p>21 Q. Uh-huh. The FDA found that the API that 22 Teva was using that entire time was adulterated, 23 though, correct?</p> <p>24 A. When do you say that occurred?</p> <p>25 Q. Well, you tell me. It's in the 483s that</p>	<p>1 But FDA still had the concern that the levels were 2 too high, so they worked with Teva to recall all 3 product.</p> <p>4 This is separate from a determination of 5 adulteration. The only time I have ever seen 6 adulteration raised in this matter is when FDA sent 7 those warning letters, as you say, to ZHP and Mylan.</p> <p>8 Q. If not adulterated, what would you call 9 all of Teva's products prior to the FDA's issuance 10 of warning letters to ZHP and Mylan?</p> <p>11 A. I would call them AB-rated and of good 12 value to the consumer.</p> <p>13 Q. Even if they contained genotoxic 14 impurities above any limit that was ever set to the 15 present?</p> <p>16 A. Well, you are getting to the core issue in 17 this matter.</p> <p>18 First of all, my claim is, and I state it 19 in my report, they were AB-rated. They were 20 pharmaceutically equivalent. They were 21 bioequivalent. They were not misbranded. They had 22 the appropriate labeling relative to the Novartis 23 reference listed drug.</p> <p>24 Now, if you have an impurity that comes to 25 light, it's a very low-level impurity, it was</p>

<p>1 unexpected, there are not analytical procedures to 2 adequately measure it, it all of a sudden comes to 3 life, does that make the product worthless? No. It 4 makes the product really fine until FDA and the 5 companies sort through what the appropriate limits 6 should be.</p> <p>7 Teva didn't do anything wrong. They were 8 making good product at their Malta and Jerusalem 9 facilities. And then FDA comes up with a limit. So 10 then you can say, okay, well, products in the 11 marketplace shouldn't have nitrosamine impurities 12 above that limit. And before all that occurred, 13 Teva had removed all product from the market.</p> <p>14 Q. Uh-huh. Are you familiar with the FDA's 15 actions against Ranbaxy concerning generic Lipitor?</p> <p>16 MS. LOCKARD: Outside the scope.</p> <p>17 THE WITNESS: You know, I could probably 18 be reminded of it, and please do if you think it 19 would be helpful -- if you think it would be 20 helpful, please remind me of that.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Sure. I'll mark Exhibit 12.</p> <p>23 (Whereupon, Exhibit 12 was marked for 24 identification.)</p> <p>25</p>	<p>Page 210</p> <p>1 MS. LOCKARD: It is 12:45 here. I don't 2 know, how long have been we been on the record, 3 Ms. Videographer, can you say?</p> <p>4 MR. HARKINS: Two hours since the last 5 break.</p> <p>6 MS. LOCKARD: Two hours since the last 7 break, so let's ask the questions about this, and 8 then --</p> <p>9 THE VIDEOGRAPHER: An hour 35 since the 10 last break.</p> <p>11 MS. LOCKARD: You need a new watch.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Let me know when you can see this exhibit, 14 sir. I'm trying to screen-share now, if that helps 15 as well.</p> <p>16 A. Okay. I see the screen share.</p> <p>17 Q. All right. And you see this is a 18 Department of Justice announcement, May 13, 2013?</p> <p>19 A. Yes, I do see this, and I'm familiar with 20 this fine.</p> <p>21 Q. Right. And you are familiar that the DOJ 22 fined Ranbaxy, a generic drug manufacturer, 500 23 million relating to cGMP violations and false 24 statements?</p> <p>25 A. Yes, I do see that.</p>
<p>Page 211</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Unfortunately, I don't think it's in your 3 binder, but it's relatively short. Let me know when 4 you can see it.</p> <p>5 A. I think it's coming to me; is that right?</p> <p>6 MS. LOCKARD: It's not in the binder, so 7 it's only on video screen.</p> <p>8 THE WITNESS: And I don't see it on the 9 video screen yet.</p> <p>10 (Whereupon, a brief discussion off the 11 record.)</p> <p>12 MR. STANOCH: What are you whispering to 13 your counsel about, Doctor?</p> <p>14 MS. LOCKARD: He asked me to remind him of 15 your name, and I said Stanoch.</p> <p>16 THE WITNESS: I'm sorry. I had a senior 17 moment.</p> <p>18 MR. STANOCH: Oh, it's okay, Doctor. I 19 wasn't going to call you out before, and I apologize 20 I did now. It's a long day.</p> <p>21 MS. LOCKARD: You are right. I should not 22 be whispering. I should have done it louder.</p> <p>23 MR. STANOCH: It's a --</p> <p>24 THE WITNESS: Well, I apologize, too. I 25 may be getting hypoglycemic.</p>	<p>Page 213</p> <p>1 Q. Right. And can you still see it?</p> <p>2 A. I do see it, yes, thank you.</p> <p>3 Q. Oh, good. I just wanted to make sure you 4 were able to look at it. And you can look at this 5 document all you want, sir, but the issue here is 6 Ranbaxy, I think, was making generic Lipitor, and it 7 was found to contain pieces of glass, right?</p> <p>8 A. I would have to read more closely to see 9 the pieces of glass, but I'll take your word for it. 10 Go ahead.</p> <p>11 Q. Okay. And so would you call generic 12 Lipitor that contained pieces of glass AB-rated?</p> <p>13 A. Well, we're getting into what causes the 14 FDA to remove an AB rating. An AB rating relates to 15 the review process. So, yes, I would say it's 16 AB-rated.</p> <p>17 Now, after it's in the market and you find 18 something objectionable or it fails a specification 19 or it's not in conformance with GMPs, it needs to be 20 withdrawn from the market.</p> <p>21 Q. So would you --</p> <p>22 A. And that's what happened here.</p> <p>23 Q. So would you consider Ranbaxy's generic 24 Lipitor that contained pieces of glass adulterated 25 prior to the date of its guilty plea?</p>

<p>1 A. It's not my decision. It's an agency 2 decision. Did the agency make a judgment of 3 adulteration?</p> <p>4 Q. Well, that's what I'm asking you, sir.</p> <p>5 A. I don't see it here. If you can point it 6 out to me, I would be glad to offer an opinion.</p> <p>7 Q. Uh-huh. It says right there --</p> <p>8 A. And I don't --</p> <p>9 Q. -- in the first paragraph about the 10 "distribution of certain adulterated drugs."</p> <p>11 A. Yes, adulterated drugs, okay. So there 12 the agency is making a decision that the drugs were 13 adulterated.</p> <p>14 Q. Right. And if you look on, you know, the 15 next page here, "Ranbaxy USA admitted to introducing 16 into interstate commerce certain batches of 17 adulterated drugs that were produced at Paonta Sahib 18 in 2005 and 2006." You see that?</p> <p>19 A. Wait a minute. I'm trying to catch up 20 with where you are reading. What paragraph are you 21 in?</p> <p>22 Q. Second full paragraph of the second page.</p> <p>23 A. Oh. Yes, I see that. And your question, 24 I'm sorry, is?</p> <p>25 Q. Right. So you see here, right, that</p>	<p>Page 214</p> <p>1 questions.</p> <p>2 Q. Right. The FDA said at a later point that 3 the drugs you had been selling since 2005 were 4 adulterated, right?</p> <p>5 A. FDA can make a certain decision in time. 6 But in this case, FDA made the decision when it 7 issued the warning letters for ZHP and Mylan.</p> <p>8 Q. Right. And it said in that decision that 9 the valsartan API that you have been making up until 10 this point is adulterated, correct?</p> <p>11 A. No, I'm not agreeing with that.</p> <p>12 Q. So --</p> <p>13 A. I'm saying FDA had -- I'm saying Teva had 14 recalled all product before the agency determination 15 of adulteration.</p> <p>16 Q. So the fact that Teva was selling product 17 that the FDA later said contained adulterated API, 18 you are saying that has no effect on whether or not 19 Teva was selling adulterated products?</p> <p>20 A. You know, I think we're confusing a lot of 21 issues here. First of all, we have to look at the 22 warning letters to ZHP and Mylan. And I'm glad to 23 discuss those if you want to give them to me as 24 exhibits.</p> <p>25 But FDA made the general statement that</p>
<p>Page 215</p> <p>1 Ranbaxy admitted that it was selling batches of 2 adulterated drugs produced at a facility in 2005 and 3 2006, right?</p> <p>4 A. Yes.</p> <p>5 Q. And that is, what, seven or eight years 6 prior to its guilty plea per this notice of 7 May 13th, 2013, right?</p> <p>8 A. I'm trying to stay up with your dates.</p> <p>9 Okay. Yes, I see the dates you are emphasizing.</p> <p>10 Q. Right. So Ranbaxy was pleading guilty 11 that it was selling adulterated products for nearly 12 ten years prior to the institution of regulatory 13 action against it, right?</p> <p>14 A. Yes. I see that.</p> <p>15 Q. But it sounds like you are telling me that 16 you would not consider any of that Ranbaxy product 17 adulterated up and until the point where the FDA 18 actually issued a warning letter; is that right?</p> <p>19 A. No, the way I read this, I think Ranbaxy 20 stated their drugs were adulterated in 2005, 2006, 21 and that's an agency determination.</p> <p>22 Q. Right. They retrospectively made that 23 determination?</p> <p>24 A. Well, I don't know if it is retrospective 25 or not, but -- go on. I'll try to answer your</p>	<p>Page 217</p> <p>1 products -- or drug substances produced at ZHP were 2 adulterated within the meaning of the act because of 3 GMP violations. I would have to see it. I'm not 4 even sure it mentions nitrosamines --</p> <p>5 Q. Uh-huh. Okay.</p> <p>6 A. -- or the fact that the products 7 containing nitrosamines were adulterated.</p> <p>8 Q. Okay. Let's take out nitrosamines. So 9 Teva selling valsartan that contained API that the 10 FDA eventually said was adulterated because of cGMP 11 violations has no impact on whether Teva's product 12 was adulterated?</p> <p>13 A. Well, I would -- is it possible to look at 14 the ZHP warning letter?</p> <p>15 Q. If you have a copy there, sir, go ahead.</p> <p>16 I don't know if I have it.</p> <p>17 A. It's not in your exhibits?</p> <p>18 MS. LOCKARD: We have a copy of it.</p> <p>19 THE WITNESS: I don't think I cited it in 20 my report. I don't think it's in a --</p> <p>21 MS. LOCKARD: There is no question 22 pending, so you don't have to answer.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Uh-huh. Did you cite the ZHP warning 25 letter from the FDA in your report, sir?</p>

<p>1 A. I don't think it's in my materials cited.</p> <p>2 I don't recall seeing it there. And that's true</p> <p>3 also for Mylan. So --</p> <p>4 Q. Okay. Well, we will figure that out.</p> <p>5 Let's put all this aside for now, and we can come</p> <p>6 back to it, but we want to go --</p> <p>7 (Whereupon, a brief discussion off the</p> <p>8 record.)</p> <p>9 THE VIDEOGRAPHER: Okay. We are going off</p> <p>10 the record. The time is 12:51.</p> <p>11 (Whereupon, a brief recess was taken.)</p> <p>12 THE VIDEOGRAPHER: Okay. We are coming</p> <p>13 back on the record. The time on the video monitor</p> <p>14 is 1:34. Please begin.</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Welcome back, Dr. Williams.</p> <p>17 A. Thank you, Mr. Stanoch.</p> <p>18 Q. During our lunch break did you speak with</p> <p>19 anyone besides your counsel there with you in San</p> <p>20 Francisco?</p> <p>21 A. No, I didn't.</p> <p>22 Q. Did you text or e-mail anybody about your</p> <p>23 testimony today?</p> <p>24 A. No, not at all.</p> <p>25 Q. And did you review any documents?</p>	<p>Page 218</p> <p>1 trying to market in the U.S. a new generic</p> <p>2 combination product that includes valsartan?</p> <p>3 MS. LOCKARD: Objection. Foundation.</p> <p>4 THE WITNESS: Was that a question,</p> <p>5 Mr. Stanoch?</p> <p>6 BY MR. STANOCH:</p> <p>7 Q. Yes. Did your opinions in any way relate</p> <p>8 to the fact that Teva is trying to market in the</p> <p>9 U.S. a new generic combination product that includes</p> <p>10 valsartan?</p> <p>11 A. No, not at all.</p> <p>12 Q. Uh-huh. Uh-huh. Do you think it would be</p> <p>13 pertinent to your opinions in this case if you were</p> <p>14 to eventually evaluate the testing and other</p> <p>15 parameters that Teva is applying for its new generic</p> <p>16 combination product that includes valsartan that it</p> <p>17 may introduce in the U.S.?</p> <p>18 MS. LOCKARD: Objection. Confusing.</p> <p>19 THE WITNESS: No, I can't see how that</p> <p>20 would have any impact on my report --</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Uh-huh.</p> <p>23 A. -- and it certainly wouldn't change my</p> <p>24 opinions.</p> <p>25 Q. Well, would you like to know what testing</p>
<p>Page 219</p> <p>1 A. We did not.</p> <p>2 Q. Okay. Thank you.</p> <p>3 Could you describe for me what it means</p> <p>4 that your expert report is only for class</p> <p>5 certification and not for liability?</p> <p>6 A. My understanding is the liability</p> <p>7 litigation will occur later, and right now we're</p> <p>8 looking at class certification that relates to</p> <p>9 economic loss for individual plaintiffs and also</p> <p>10 large payors.</p> <p>11 Q. Uh-huh. Right. And prior to the break we</p> <p>12 were talking a little bit about the Teva recalls,</p> <p>13 and I think you said that Teva had recalled all of</p> <p>14 its valsartan product from the market and has not</p> <p>15 reintroduced it, correct?</p> <p>16 A. Yes, that's true, Mr. Stanoch.</p> <p>17 Q. Okay. Are you aware of whether Teva has</p> <p>18 been undertaking to introduce a new generic</p> <p>19 combination product that includes valsartan?</p> <p>20 A. You know, I believe in the course of some</p> <p>21 of my research or discussions with counsel, I did</p> <p>22 hear that. But I know very little about what they</p> <p>23 are doing, and it's certainly not in my report.</p> <p>24 Q. Okay. I was going to say, do your</p> <p>25 opinions in any way relate to the fact that Teva is</p>	<p>Page 221</p> <p>1 Teva is doing of this new product under development</p> <p>2 for nitrosamines?</p> <p>3 A. I would always be interested in what Teva</p> <p>4 is doing because of their sophistication as a</p> <p>5 pharmaceutical company, but it doesn't relate to my</p> <p>6 report and it doesn't impact my opinions.</p> <p>7 Q. Uh-huh. But if Teva is testing for</p> <p>8 nitrosamines now for a new product in ways that were</p> <p>9 available to it prior to 2018, that would be</p> <p>10 pertinent, would it not?</p> <p>11 MS. LOCKARD: Objection. Speculation.</p> <p>12 Foundation.</p> <p>13 THE WITNESS: Well, the way I would try to</p> <p>14 couch it in terms of my report is Teva should be</p> <p>15 following the 2021 guidance on nitrosamine</p> <p>16 impurities, and how they deal with those</p> <p>17 recommendations from FDA, as I say, would be of</p> <p>18 scientific interest to me, but not pertinent to my</p> <p>19 report.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. That's fair. Do you know whether Teva is</p> <p>22 following the FDA 2021 guidance on nitrosamine</p> <p>23 impurities regarding its development of a new</p> <p>24 valsartan combination product for the U.S. market?</p> <p>25 A. Do I know what about that? I'm sorry.</p>

<p>1 Q. Do you know whether Teva -- or strike 2 that.</p> <p>3 Do you know how, if at all, Teva is 4 following the FDA 2021 guidance on nitrosamine 5 impurities regarding Teva's development of a new 6 valsartan combination product for the U.S. market?</p> <p>7 A. No, I have no idea, and I'm sure Teva 8 might regard that as confidential information.</p> <p>9 Q. Uh-huh. You reference throughout your 10 report, and we can look at particular paragraphs, 11 pharmaceutically equivalent and bioequivalent; is 12 that right?</p> <p>13 A. Yes, I do speak to those points, 14 Mr. Stanoch.</p> <p>15 Q. Okay. And we can look -- you can look at 16 any paragraph you like, but you can look at, say, 17 Paragraph 60, where you mention both these terms, if 18 that's helpful.</p> <p>19 A. Okay. Thank you. I'll go to Paragraph 20 60. Okay. And that's on page 19?</p> <p>21 Q. Yes. Are you there?</p> <p>22 A. Yes, I am, sir.</p> <p>23 Q. Okay. Now, what do you mean by 24 "bioequivalent," as you use the term in your report?</p> <p>25 A. Well, it's a requirement for a generic</p>	<p>Page 222</p> <p>1 equivalence means both pharmaceutically equivalent 2 and bioequivalent.</p> <p>3 Q. Uh-huh. Isn't it true, Doctor, that 4 therapeutic equivalence includes pharmaceutical 5 equivalence, bioequivalence, as well as having the 6 same clinical effect and safety profile?</p> <p>7 A. No, I wouldn't add that, Mr. Stanoch. I 8 think the purpose of the bioequivalence study is to 9 say the bioequivalence study substitutes for 10 assessment of clinical safety and efficacy.</p> <p>11 Q. Okay. Let's look at the next exhibit. 12 Stand by.</p> <p>13 This will be Exhibit 13. It's Tab 10 in 14 your binder, sir.</p> <p>15 (Whereupon, Exhibit 13 was marked for 16 identification.)</p> <p>17 BY MR. STANOCHE:</p> <p>18 Q. Let me know when you are there.</p> <p>19 A. Okay. I'm looking at the Orange Book 20 preface.</p> <p>21 Q. Right. This is a copy of the Orange Book 22 preface, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And you are certainly familiar with the 25 Orange Book, I take it, right?</p>
<p>Page 223</p> <p>1 manufacturer to show bioequivalence between their 2 proposed product and the reference listed drug. And 3 it's expressed in law and regulations as an absence 4 of difference in terms of the rate and extent of the 5 generic product compared to the reference listed 6 drug.</p> <p>7 Q. What do you mean by the term 8 "pharmaceutically equivalent" as used in your 9 report?</p> <p>10 A. Well, if you, again, look at the law and 11 regulations, "pharmaceutical equivalence" means the 12 same active ingredient; different impurities, 13 possibly; the same dose form; the same strength; and 14 the same route of administration.</p> <p>15 So the two terms together, if they are met 16 by a generic manufacturer, allow the agency to 17 declare that the products are therapeutically 18 equivalent, and if those requirements are satisfied, 19 among other things, then FDA can give an AB rating 20 in the Orange Book.</p> <p>21 Q. And then I think in this paragraph, the 22 second sentence, you explain what you mean by 23 therapeutic equivalence; is that right?</p> <p>24 A. Yes, and I may have gotten a little bit 25 ahead of your questioning, but therapeutic</p>	<p>Page 225</p> <p>1 A. Yes.</p> <p>2 Q. And what is the Orange Book?</p> <p>3 A. It's an FDA publication entitled Approved 4 Drug Products with Therapeutic Equivalence 5 Evaluations. And then after that, we always say, 6 "commonly referred to as the Orange Book." And the 7 reason for that, it is an orange book.</p> <p>8 I even know how it came to have the color 9 orange. It was actually created around the time of 10 Halloween, so that's why it's colored orange.</p> <p>11 But it lists the FDA-approved products 12 approved under the NDA/ANDA system.</p> <p>13 I'll stop there, Mr. Stanoch.</p> <p>14 Q. Okay. I appreciate that answer, including 15 the color commentary on the Orange Book, Doctor.</p> <p>16 If you can turn to the section 1.2, 17 "Therapeutic Equivalence-Related Terms."</p> <p>18 A. Yeah, I'm getting there. 1.1.</p> <p>19 Okay. I'm there.</p> <p>20 Q. And this section talks about certain 21 terms. Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. And one of those terms is "therapeutic 24 equivalents," correct?</p> <p>25 A. Yes. Under 1.2.</p>

<p>Page 226</p> <p>1 Q. Yes. And could you just read us that 2 first paragraph there for "Therapeutic Equivalents," 3 where it says, "Approved drug products are?" 4 A. "Are drug products in identical dosage 5 forms and route(s) of administration" and "contain 6 identical amounts" -- 7 Q. Oh, oh. Oh, oh, oh, oh, Doctor. I'm 8 sorry to stop you. I was trying to direct you to 9 the paragraph that is there for "Therapeutic 10 Equivalents." Do you see that a little down? 11 A. Oh, sure. Down below? 12 Q. Yes. And just that -- it's three lines, 13 the first paragraph. Do you see that? 14 A. Yeah, where it says, "Approved drug 15 products"?</p> <p>16 Q. Yes, sir. Could you just read that 17 paragraph?</p> <p>18 A. Sure. "Approved drug products are 19 considered to be therapeutic equivalents if they are 20 pharmaceutical equivalents for which bioequivalence 21 has been demonstrated, and they can be expected to 22 have the same clinical effect and safety profile 23 when administered to patients under the conditions 24 specified in the labeling."</p> <p>25 Q. Right. And that second clause there that</p>	<p>Page 228</p> <p>1 look through it, that you don't mention anything 2 about a therapeutic equivalent having the same 3 clinical effect and safety profile. 4 A. Well -- 5 Q. Why did you leave that part out? 6 A. You know, Mr. Stanoch, I have to say, it's 7 an unimportant question. I think everybody knows 8 that if you show pharmaceutical equivalence and 9 bioequivalence, you then are allowed to have the 10 same labeling as the reference listed drug, 11 substantively, and this means you will have the same 12 clinical effect and safety. 13 I don't know why you are questioning my 14 words in my report, so perhaps you can explain that 15 at the right time. 16 Q. Well, we can agree that your Paragraph 60 17 does not include the words "same clinical effect and 18 safety profile," right? 19 A. No, and it's certainly understood, and I 20 think any reasonable person would understand, what I 21 meant when I talked about pharmaceutical equivalence 22 and bioequivalence. 23 Q. So show me in Paragraph 60 where those 24 words appear then, Doctor. 25 A. Which words?</p>
<p>Page 227</p> <p>1 you read, that is something that is absent from your 2 characterization of therapeutic equivalence in 3 Paragraph 60 of your report, correct? 4 A. Yes. I think -- my hope -- everything is 5 aligned and in agreement, but that is what I mean 6 when I made those statements in Paragraph 60. 7 Q. And earlier I think you said that same 8 clinical effect and safety is not part of 9 therapeutic equivalence. Are you changing your 10 testimony that you agree that a therapeutic 11 equivalent can be expected to have the same clinical 12 effect and safety profile when administered to 13 patients under the conditions specified in the 14 label? 15 A. Well, I think, without quibbling with you, 16 Mr. Stanoch, what I was trying to say is in terms of 17 the application process, the demonstration is the 18 end of the sentence. And if those two types of 19 equivalence are demonstrated, then, as you want to 20 go on and say, they can be expected to have the same 21 clinical effect and safety. But in terms of the 22 concept of therapeutic equivalence, it stops with 23 demonstration. 24 Q. Well, because I don't see anywhere in your 25 report, doing a word search, and you can certainly</p>	<p>Page 229</p> <p>1 Q. "Same clinical effect and safety profile." 2 A. I don't say that. That's what therapeutic 3 equivalence means. 4 Q. Uh-huh. 5 A. "Therapeutic equivalence" are the same 6 words as "same clinical effect and safety profile." 7 Q. Uh-huh. Right. And those words do not 8 appear anywhere in your report, though? 9 A. "Therapeutic equivalence" appears there, 10 and it means the same thing as identical safety and 11 efficacy outcomes. That's what it means to have the 12 same labeling as the reference listed drug. 13 Q. Well, Doctor, I want to make sure we're 14 not talking past each other. I'm looking at your 15 Paragraph 60, and it says, "Therapeutic equivalence 16 means that the drug is pharmaceutically equivalent 17 and bioequivalent for the same use," period; is that 18 right? 19 A. Mr. Stanoch, I just really am not 20 following your line of questioning. Can you be more 21 clear? 22 Q. Oh, absolutely, Doctor. I'm looking at 23 the words you wrote. 24 A. I think I'm -- 25 Q. So let's look at Paragraph -- go ahead.</p>

<p>1 A. Mr. Stanoch, let me finish my answer. 2 Q. Please. 3 A. I think I am perfectly clear here. 4 Anybody would understand what I'm saying who 5 understands generic substitution. Now, what is it 6 about my statement or my words that you are not 7 getting? 8 Q. I'm getting it about the words that are 9 not there, Doctor, that's my first step. I'm 10 looking at Paragraph 60. Can we agree -- 11 A. Well -- 12 Q. Let me finish my question, Doctor, I let 13 you finish your answer, please. 14 Your Paragraph 60, when you're defining 15 therapeutic equivalence, you say, "Therapeutic 16 equivalence means that the drug is pharmaceutically 17 equivalent and bioequivalent for the same use," 18 period, correct? 19 A. I don't think you are reading my words 20 correctly. 21 Q. Well, you turn to Paragraph 60, 22 Dr. Williams. 23 A. Would you please try to read my words 24 correctly? 25 Q. Why don't you read Paragraph 60 to me,</p>	<p>Page 230</p> <p>1 report, correct? 2 A. I don't need to write it in my report. 3 It's not pertinent. It's unnecessary. 4 Q. Uh-huh. And does valsartan containing 5 nitrosamine impurities have the same safety profile 6 as valsartan that do not have nitrosamine 7 impurities? 8 A. Impurities are not a determinant of either 9 pharmaceutical equivalence or bioequivalence, and 10 that would include nitrosamine impurities. 11 Q. We're talking therapeutic equivalence now, 12 aren't we? 13 A. I don't know. Is that your question? 14 Q. That's what we have been talking about, 15 Dr. Williams. Let me ask it again. 16 Do you believe valsartan containing 17 nitrosamines have the same safety profile as 18 valsartan that does not contain any nitrosamines? 19 A. Okay. 20 MS. LOCKARD: Objection. Form of the 21 question. Vague. 22 THE WITNESS: That is a different 23 question. And I would say, with appropriate limits, 24 yes, the answer to your question is yes. 25</p>
<p>1 Dr. Williams? 2 A. All right. I'll be glad to. "Generic 3 drugs that are pharmaceutically equivalent and 4 bioequivalent to the" reference listed drug and "are 5 deemed therapeutically equivalent and are 6 interchangeable with the" reference listed drug. 7 Now, what part of that don't you understand? 8 Q. Please keep reading, Doctor. 9 A. "Therapeutic equivalence means" "the drug 10 is pharmaceutically equivalent and bioequivalent for 11 the same use." We're talking about the labeling. 12 In other words, if you're pharmaceutically 13 equivalent and bioequivalent, you get to use the 14 same labeling as the referenced listed drug. If you 15 have the same labeling, you will necessarily have 16 the same clinical effect and safety profile. 17 I think these words are almost 18 self-evident, and I really wonder why I haven't been 19 clear about it with you. 20 Q. Doctor, I'm asking you to tell us where in 21 Paragraph 60 you write that therapeutic equivalence 22 can be expected to have the same clinical effect and 23 safety profile? 24 A. I don't write it. I never said I did. 25 Q. And you don't write it anywhere in your</p>	<p>Page 231</p> <p>1 BY MR. STANOCH: 2 Q. Well, what do you mean by "appropriate 3 limits"?</p> <p>4 A. Well, for example, the interim limits that 5 FDA set in December 2018 for -- 6 Q. In absence of those limits, do you believe 7 valsartan containing nitrosamines has the same 8 safety profile as valsartan that does not contain 9 any nitrosamines?</p> <p>10 A. Are you asking my personal opinion? Or 11 are you asking me as part of my report?</p> <p>12 Q. You are the one opining on therapeutic 13 equivalence, Doctor, so I'm asking you, both in your 14 opinions and in your personal knowledge.</p> <p>15 A. I would say it would have the same 16 therapeutic outcome in terms of safety and efficacy. 17 If somebody wants to give data that suggests 18 otherwise, the FDA could look at that data.</p> <p>19 Q. Uh-huh. You are talking about therapeutic 20 outcomes, you are referring to whether the drug 21 works for its intended purpose, right?</p> <p>22 A. I would say when we look at these words, 23 yes, we are talking about the valsartan molecule.</p> <p>24 Q. Right. And still the issue we're trying 25 to get at here, Doctor, is: In the absence of</p>

<p>Page 234</p> <p>1 interim limits, do you believe valsartan containing 2 nitrosamines, which you have agreed is part of the 3 cohort of concern, has the same safety profile as 4 valsartan that does not contain nitrosamines?</p> <p>5 A. Well, let's back up a little bit. First 6 of all, we understand that the impurity profile can 7 be different in the drug substance of the generic 8 compared to the reference listed drug. And there 9 could be many, many impurities in those two drug 10 substances with unknown pharmacologic effects.</p> <p>11 When you see a particular impurity of 12 concern, you would like to put a limit on it, 13 including whether it's a genotoxic impurity or not. 14 That's the whole idea behind reporting, 15 identification, and qualification.</p> <p>16 I think nitrosamine impurities here are 17 part of the general approach to impurity handling. 18 So I would say if nitrosamine impurities are handled 19 the way other impurities are handled in the world of 20 generic substitution, yes, you would get the same 21 safety and efficacy outcomes.</p> <p>22 Q. What if they are not handled in the way 23 other impurities are handled?</p> <p>24 A. Well, if I don't -- can you be more 25 specific in your question in terms of how they would</p>	<p>Page 236</p> <p>1 commonly found in foodstuffs and they can be allowed 2 in chemically synthesized drugs at certain levels. 3 And the goal here of this whole effort really has 4 been to identify them and make sure they do not 5 exceed those levels.</p> <p>6 BY MR. STANOCH:</p> <p>7 Q. Would you advise patients to keep taking 8 recalled valsartan products?</p> <p>9 MS. LOCKARD: Objection. Speculation.</p> <p>10 Outside the scope.</p> <p>11 THE WITNESS: Well, that seems a very odd 12 question since they were recalled. Is that a 13 hypothetical?</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Well, we are just trying to say what you 16 would do with a patient, Doctor. And by the way, 17 you are a doctor, correct?</p> <p>18 A. That's right.</p> <p>19 Q. You have an active medical license, 20 correct?</p> <p>21 A. I do not.</p> <p>22 Q. You do not. When was your medical license 23 last active?</p> <p>24 A. In 1990. I stopped treating patients 25 clinically when I went to FDA in 1990.</p>
<p>Page 235</p> <p>1 be handled differently?</p> <p>2 Q. Sure. Prior to June 2018, assume there is 3 valsartan that contains nitrosamines and valsartan 4 that does not contain nitrosamines. Do they have 5 the same safety profile?</p> <p>6 A. We just don't know that.</p> <p>7 Q. So then how --</p> <p>8 A. I mean, for all I know, the valsartan drug 9 substances that contain nitrosamine may have been at 10 perfectly safe levels. I just don't know that.</p> <p>11 Q. Uh-huh.</p> <p>12 A. FDA finally decided they need to be below 13 certain interim limits. But even there, I think FDA 14 would say the risk was very low and that their 15 limits were very conservative. So you are asking a 16 question that would be very difficult to answer.</p> <p>17 Q. Uh-huh. Well, in the real world, Doctor, 18 right, if you go to a patient and you say to the 19 patient, do you want this valsartan that contains 20 nitrosamines or do you want this valsartan that does 21 not contain nitrosamines, what do you advise your 22 patient?</p> <p>23 MS. LOCKARD: Objection. Outside the 24 scope of his expertise.</p> <p>25 THE WITNESS: I would say nitrosamines are</p>	<p>Page 237</p> <p>1 Q. Uh-huh. Uh-huh. And would you advise a 2 patient, if given the choice, to take valsartan that 3 contained nitrosamines or valsartan that did not 4 contain nitrosamines?</p> <p>5 MS. LOCKARD: Objection. Outside the 6 scope of his expert report and opinions.</p> <p>7 THE WITNESS: You know, it's a 8 hypothetical. I'm going to give you an answer that 9 may not seem appropriate.</p> <p>10 But I worked once with a very 11 sophisticated chemist at FDA who said you get more 12 impurities in the back of a Washington, D.C., bus 13 than you will ever get from your medicines.</p> <p>14 So, you know, it's a question of risk, 15 relative risk, severity of risk, and I just don't 16 think I can answer your question.</p> <p>17 BY MR. STANOCH:</p> <p>18 Q. You have a -- oh, sorry. Go ahead.</p> <p>19 A. I would say to patients, FDA will control 20 impurities within the -- nitrosamine impurities 21 within your medical products appropriately in 22 accordance with the new guidance.</p> <p>23 Q. Uh-huh. Prior to the FDA guidance in 24 December 2018, right, would you advise a patient to 25 take valsartan with nitrosamines or the valsartan</p>

<p>1 without nitrosamines?</p> <p>2 A. Well, let me point out that FDA told 3 people to keep on taking their valsartan products 4 before the interim limits were set.</p> <p>5 Q. And that was so they don't drop dead of a 6 heart attack, correct?</p> <p>7 MS. LOCKARD: Objection. Speculation.</p> <p>8 THE WITNESS: I would not say that it way.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Right. Because they did not want to go 11 off your medication for hypertension abruptly until 12 you had a substitute; isn't that right, Doctor?</p> <p>13 A. Well, they did not want people to abruptly 14 stop their medicines containing valsartan.</p> <p>15 Q. Absolutely correct. But don't you think 16 the idea there was: Don't abruptly stop, but you 17 should probably get a different valsartan product or 18 other substitute as soon as you can?</p> <p>19 MS. LOCKARD: Objection. Speculation.</p> <p>20 Outside the scope of his expert testimony and this 21 report.</p> <p>22 THE WITNESS: I'll just stand by what FDA 23 said. They said, don't -- you know, the risk here 24 is very low. The recall classification risk was 25 low. And they were saying, don't stop your</p>	<p>Page 238</p> <p>1 Can you imagine how many patients you 2 would have to study to see a difference even if it 3 existed?</p> <p>4 Q. Let's talk about today, right. The FDA 5 limits for nitrosamines exist today, right?</p> <p>6 A. Yes.</p> <p>7 Q. Does a valsartan drug that contains 8 nitrosamines above those limits have the same safety 9 profile as a valsartan drug with nitrosamines below 10 those limits?</p> <p>11 A. Far as I know, they have the same safety 12 and efficacy outcomes.</p> <p>13 Q. So then what is the point of the interim 14 limits, then, which say, if you have more than this, 15 you can't sell it?</p> <p>16 A. You have to set some kind of limits.</p> <p>17 That's what an impurity is. An impurity needs a 18 limit.</p> <p>19 Q. But you just said, Doctor, that a 20 valsartan product with nitrosamines above the limits 21 as they exist today is just as safe as one that has 22 nitrosamines below the limit, didn't you?</p> <p>23 A. I have no understanding that it has a 24 different safety profile in terms of any kind of 25 risk.</p>
<p>Page 239</p> <p>1 valsartan medicines abruptly under these 2 circumstances.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Uh-huh. All right. So let's go back to 5 the safety profile one more time, Doctor. You are 6 not going to tell us whether you think a valsartan 7 with nitrosamines might have a different safety 8 profile than a valsartan without nitrosamines?</p> <p>9 A. I absolutely don't know, and to answer 10 that question would be a very difficult comparative 11 clinical trial.</p> <p>12 Q. Uh-huh. Well, let's say right now with -- 13 let's say today --</p> <p>14 MS. LOCKARD: Wait. Hold on a minute. 15 Let him --</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Oh, go ahead, Doctor.</p> <p>18 A. And if you think about what it would take 19 to answer that question, imagine a comparative 20 clinical trial where you have patients randomized 21 between two valsartan-containing products, one with 22 one limit set by FDA and one with no limits before 23 FDA set limits. Imagine the outcome of that 24 clinical trial. I think it would be very hard to 25 see a difference.</p>	<p>Page 241</p> <p>1 Q. If not for safety, Doctor, then why is the 2 FDA setting limits for nitrosamines in the first 3 place?</p> <p>4 A. They need to set a limit for the impurity, 5 and they base it on that M7 guidance in terms of how 6 you set limits for genotoxic impurities.</p> <p>7 Q. Which is --</p> <p>8 A. Remember, it's a very difficult decision 9 because nitrosamine impurities are present in food 10 and foodstuffs and in the environment, in the water. 11 And you saw it in the M7 guidance. How do you set 12 limits when that kind of impurity is present all 13 around us, if you will?</p> <p>14 FDA has to do something. They do it out 15 of an abundance of caution. But it doesn't mean 16 that something above the limit was therefore toxic.</p> <p>17 Q. You can't sell a product today that is 18 above the nitrosamine limits, correct?</p> <p>19 A. Well, I'll generally agree with you, but I 20 will also say that in the guidance they say you can 21 be above limits under certain circumstances with FDA 22 approval.</p> <p>23 Q. Are you aware of any manufacturer who has 24 sought FDA approval to sell a product with 25 nitrosamines above the now-current limits?</p>

<p style="text-align: right;">Page 242</p> <p>1 A. No, I am not.</p> <p>2 Q. Uh-huh. And you are telling me that the</p> <p>3 FDA limits on nitrosamines have nothing to do with</p> <p>4 the safety of the drug; is that your testimony</p> <p>5 today, sir?</p> <p>6 A. I think they have to do with reducing</p> <p>7 risk, and that is how FDA would state it in terms of</p> <p>8 the M7 guidance and also the nitrosamine guidance.</p> <p>9 Q. Risk of what?</p> <p>10 A. But that risk is very difficult to</p> <p>11 quantify.</p> <p>12 Q. Risk of what?</p> <p>13 A. Risk of whatever a nitrosamine impurity</p> <p>14 might do.</p> <p>15 Q. Uh-huh. What might it do?</p> <p>16 MS. LOCKARD: Objection. Speculation.</p> <p>17 Outside the scope of his opinions.</p> <p>18 THE WITNESS: I'm sorry. Was that a</p> <p>19 question, Mr. Stanoch? I didn't hear it.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Yes, sir. What might it do, the risk?</p> <p>22 A. Well, you can see it in the M7 guidance,</p> <p>23 that it has the propensity in certain settings to</p> <p>24 cause cancer.</p> <p>25 Q. Right. Right. The purpose of the FDA's</p>	<p style="text-align: right;">Page 244</p> <p>1 with nitrosamines below the limit or quantified at</p> <p>2 zero?</p> <p>3 MS. LOCKARD: Objection. Outside the</p> <p>4 scope of his opinions.</p> <p>5 THE WITNESS: I'm saying that</p> <p>6 hypothetically that could easily be possible.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Uh-huh. Okay. Let's look at the exhibit</p> <p>9 some more. The next paragraph, do you see where it</p> <p>10 reads, "FDA classifies as therapeutically</p> <p>11 equivalent"? Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And then it lists a number of criteria</p> <p>14 which the Orange Book says the FDA classifies for</p> <p>15 purposes of therapeutic equivalence, right?</p> <p>16 A. Yes. Are you reading that final paragraph</p> <p>17 on this page?</p> <p>18 Q. Yes, sir. The sentence reads, "FDA</p> <p>19 classifies as therapeutically equivalent those drug</p> <p>20 products that meet the following general criteria";</p> <p>21 do you see that?</p> <p>22 A. Yes, I do, and then it goes one, two,</p> <p>23 three -- I guess the last one is four -- five. It</p> <p>24 continues on, and I think it ends with five.</p> <p>25 Q. Yes, sir. I agree with that.</p>
<p style="text-align: right;">Page 243</p> <p>1 limits currently is because there is a risk, however</p> <p>2 quantified, to a patient if they take a pill that</p> <p>3 has nitrosamines above the limit, right?</p> <p>4 MS. LOCKARD: Objection. That's far</p> <p>5 outside the scope of his opinions. He's not giving</p> <p>6 a causation opinion.</p> <p>7 THE WITNESS: Yeah, I am not definitely</p> <p>8 not getting into causation.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. I'm not asking you either that, Doctor.</p> <p>11 What we're trying to understand here now is the</p> <p>12 safety profile of a drug that has nitrosamines above</p> <p>13 the limit. And you were telling me, correct me if</p> <p>14 I'm wrong, that it has nothing to do with safety,</p> <p>15 correct?</p> <p>16 A. No, I'm saying I don't know if there is a</p> <p>17 difference between the safety profile of the two</p> <p>18 products.</p> <p>19 Q. So --</p> <p>20 A. It may be exactly the same, and to prove</p> <p>21 that it's different would take a lot of work.</p> <p>22 That's my point.</p> <p>23 Q. Uh-huh. So you are saying that a</p> <p>24 valsartan drug with nitrosamines above the current</p> <p>25 limits may be just as safe as a valsartan product</p>	<p style="text-align: right;">Page 245</p> <p>1 And these are criteria that the Orange</p> <p>2 Book reports that the FDA uses for classifying drug</p> <p>3 products as therapeutically equivalent, correct?</p> <p>4 A. Yes.</p> <p>5 Q. All right. And one of those is Number 5,</p> <p>6 is whether the drug product is "manufactured in</p> <p>7 compliance with Current Good Manufacturing Practice</p> <p>8 regulations," correct?</p> <p>9 A. Yes, I see that.</p> <p>10 Q. And another one is 2(b), which is that the</p> <p>11 drug products "meet compendial or other applicable</p> <p>12 standards of strength, quality, purity, and</p> <p>13 identity"; did I read that correctly?</p> <p>14 A. Yes, you did.</p> <p>15 Q. Right. So for therapeutic equivalence,</p> <p>16 meaning compendial standards alone may not be</p> <p>17 sufficient per the Orange Book's guidance, correct?</p> <p>18 A. That's quite true, because sometimes there</p> <p>19 isn't a compendial standard, so in that case there</p> <p>20 would be a private, FDA-agreed standard.</p> <p>21 Q. Uh-huh. And there may be other examples</p> <p>22 as well, correct?</p> <p>23 A. Well, I don't know what you mean by that.</p> <p>24 I'm thinking of the case where there is no</p> <p>25 compendial standard.</p>

<p>1 Q. Uh-huh. And there may be standards 2 reflected in ICH or other industry guidance, 3 correct?</p> <p>4 A. No, I wouldn't go there. I'm trying to 5 think of a simple case, that many times FDA doesn't 6 have a monograph for a drug substance or a drug 7 product --</p> <p>8 Q. Uh-huh.</p> <p>9 A. -- in which case, the quality would be 10 controlled with a private specification agreed to 11 with FDA as part of the review process.</p> <p>12 Q. Uh-huh. This criteria 2(b) does not say 13 anything about the absence of a compendial standard, 14 correct?</p> <p>15 A. Well, I think it does. It says, "meet 16 compendial or other applicable standards."</p> <p>17 Q. Uh-huh.</p> <p>18 A. The other applicable standards would be 19 the private specification agreed to with FDA.</p> <p>20 Q. Uh-huh. And I think you testified about 21 this earlier, that a manufacturer can agree to 22 different specifications or standards for a drug in 23 consultation with the regulator, right?</p> <p>24 A. Yeah, I think that's generally part of 25 what I'm saying here.</p>	<p>Page 246</p> <p>1 found to be adulterated or otherwise improperly 2 marketed, right?</p> <p>3 A. Yeah. I think what we're getting at here, 4 too, is the idea that there can be recalls if a 5 product fails its specifications, and that happens 6 all the time, as I stated in my report. That 7 doesn't mean it will be taken out of the Orange Book 8 or its AB rating will be changed. I think that's 9 what we're talking about here.</p> <p>10 Q. You can put that aside for now. 11 (Whereupon, a brief discussion off the 12 record.)</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Are you aware of whether Teva has a master 15 drug file for valsartan?</p> <p>16 A. If I understand your question, 17 Mr. Stanoch, are you saying Teva makes its own 18 valsartan?</p> <p>19 Q. Right. Do you understand Teva to have a 20 drug master file for valsartan?</p> <p>21 A. Yes, thank you. 22 No, I am not aware of that. I would think 23 it would be possible.</p> <p>24 Q. Would seeing documents related to Teva's 25 own valsartan DMF be pertinent to you in terms of</p>
<p>Page 247</p> <p>1 Q. Then let's flip a few more pages. 2 Unfortunately it's not numbered, Doctor. This is 3 the section that has 1.7, "Therapeutic Equivalence 4 Evaluation Codes." Tell me when you are there.</p> <p>5 A. Okay. I'm there.</p> <p>6 Q. And if you look at the first paragraph of 7 that page, it begins in bold, "Every product in the 8 Orange Book is subject at all times to regulatory 9 action." Do you see that?</p> <p>10 A. Yes, I do, at the very top of the page.</p> <p>11 Q. And you can read that full paragraph if 12 you like, but I want to direct your attention to the 13 penultimate sentence that begins, "FDA believes that 14 retention"; do you see that?</p> <p>15 A. Yes, I do see that.</p> <p>16 Q. Could you just read that sentence, just 17 that sentence, sir?</p> <p>18 A. "FDA believes that retention of a 19 violative product in the Orange Book will not have 20 any significant adverse health consequences, because 21 other legal mechanisms are available to the Agency 22 to prevent the product's actual marketing."</p> <p>23 Q. Thank you. And that means, does it not, 24 that just because a drug is listed in the Orange 25 Book, does not mean that it's immune from being</p>	<p>Page 249</p> <p>1 whether Teva could have known about nitrosamines 2 forming as part of the API manufacturing process for 3 valsartan?</p> <p>4 MS. LOCKARD: Objection. Lacks 5 foundation.</p> <p>6 THE WITNESS: I wouldn't rule it out, but 7 I don't think -- I didn't see any documents like 8 that.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Uh-huh. Stand by. 11 Could you turn in your report, sir -- it's 12 beginning around Paragraph 120, the first Paragraph 13 120. I think it's around page 41. I don't have the 14 exact copy you have in front of you.</p> <p>15 A. 120?</p> <p>16 Q. Yes, sir.</p> <p>17 A. On page 41?</p> <p>18 Q. Yes.</p> <p>19 A. "Doctor Panagos asserts"?</p> <p>20 Q. Yes. Are you there?</p> <p>21 A. Yes, I am.</p> <p>22 Q. Great. And in this subsection, you're 23 rebutting, if you will, opinions offered by 24 Dr. Panagos, correct?</p> <p>25 A. Yes, I agree.</p>

<p>1 Q. Right. And why don't you read the first 2 couple sentences for us there in Paragraph 120?</p> <p>3 A. "Dr. Panagos asserts that the safety and 4 efficacy of a medication must be proven by the 5 manufacturer to the FDA so that the medication may 6 receive approval." I think it's a she. She 7 "further states that this information serves as a 8 warranty for the medication ensuring that it meets 9 the quality standards outlined by" "FDA."</p> <p>10 Should I stop?</p> <p>11 Q. You can stop now.</p> <p>12 A. Okay.</p> <p>13 Q. And you picked up on part of it. You 14 understand, you know, Dr. Panagos is a female, 15 correct?</p> <p>16 A. Yes, I see that now.</p> <p>17 Q. Okay. If you can scroll down, sir, to 18 Paragraph 123. Tell me when you are there.</p> <p>19 A. Yes, I see that statement.</p> <p>20 Q. Right. And it begins, "Dr. Panagos 21 describes TPPs as payors at risk for purchases of 22 affected valsartan containing drugs products."</p> <p>23 A. Yes.</p> <p>24 Q. And what are TPPs, as you refer to it 25 there?</p>	<p>Page 250</p> <p>1 are not saying that TPPs were at any sort of 2 physical risk involving valsartan, right?</p> <p>3 A. No, as I understand Dr. Panagos, she was 4 referring to financial risk.</p> <p>5 Q. Right. I would agree with that. You 6 understand that TPPs are at financial risk for 7 purchases of their, say, insureds, right?</p> <p>8 A. Yes. And now I see your point. It is two 9 different kinds of risks.</p> <p>10 Q. Well, I appreciate your clarification. I 11 think we're on the same page.</p> <p>12 And then in the next paragraph, in the 13 second sentence, you mention, "Both the TPPs and 14 patients got value for these products up to the 15 point they were recalled from the market." Do you 16 see that?</p> <p>17 A. Yes.</p> <p>18 Q. What do you mean by "value" there?</p> <p>19 A. Well, I think it gets to my general 20 opinion that these were useful products. They were 21 pharmaceutical equivalent. They were bioequivalent. 22 They were AB-rated. And practitioners and patients 23 used them successfully for the indications such as 24 hypertension.</p> <p>25 Q. Right. So are you opining on whether or</p>
<p>Page 251</p> <p>1 A. I think Dr. Panagos uses that abbreviation 2 for third-party payors.</p> <p>3 Q. What is your understanding of a 4 third-party payor in this case?</p> <p>5 A. It might be an insurance company or -- you 6 know, I'm trying to think of a term. You know, a 7 medical care organization that pays for medicinal 8 products.</p> <p>9 Q. Uh-huh. Right. And then in the next 10 sentence you talk about risk about stopping your 11 antihypertensive treatment?</p> <p>12 A. Yes.</p> <p>13 Q. Right. You are talking about two 14 different types of risk here in this paragraph, 15 aren't you?</p> <p>16 A. Well, I'm not sure I understand your 17 question. Perhaps you could continue.</p> <p>18 Q. Sure. So in the first sentence you are 19 referring to TPPs as payors at risk, right?</p> <p>20 A. Okay.</p> <p>21 Q. Right. And then later you talk about, you 22 know, risks of stopping antihypertensive treatment, 23 right?</p> <p>24 A. Yes.</p> <p>25 Q. Right. So what I'm clarifying is: You</p>	<p>Page 251</p> <p>1 not patients or TPPs received value for the 2 valsartan they purchased prior to the recalls?</p> <p>3 A. I think if you look at my concluding 4 opinions, we have to pay attention to that.</p> <p>5 Q. Of course.</p> <p>6 A. My opinions are they were not adulterated. 7 They were pharmaceutically equivalent and 8 bioequivalent, and they were AB-rated. They were 9 not misbranded.</p> <p>10 Q. Right. I'm --</p> <p>11 A. So I think I'm answering your question and 12 speaking specifically to my opinions.</p> <p>13 Q. Right. I'm looking at your conclusions, 14 Doctor, at the very last page of your report, and I 15 don't see anything about opinions on who might have 16 received what value for valsartan products, so 17 that's what I'm trying to understand here.</p> <p>18 A. I guess if I wanted to extend my 19 conclusions, my opinions to this particular 20 paragraph, I would say third-party payors got value.</p> <p>21 Q. Uh-huh. And again, you define the value 22 that the third-party payors got as what?</p> <p>23 A. In terms of getting a safe and effective 24 product that could be used to treat patients in 25 accordance with labeled indications.</p>

<p>1 Q. And you are including in your definition 2 of a safe and effective drug products that have 3 nitrosamines in them, right? 4 A. Yes. And we know the products can have 5 nitrosamines in them. 6 Q. Including products that had nitrosamines 7 above the FDA's eventual limits, correct? 8 A. Well, that's the debatable point, and I'm 9 saying I just don't know if they had any different 10 safety and efficacy compared to the products below 11 that limit. 12 Q. Got it. You are not a -- you don't know 13 one way or the other whether a valsartan drug that 14 contains nitrosamines above the now-current FDA 15 limits had a different safety profile than valsartan 16 with nitrosamines below the now-current limits? 17 A. I think you are stating that correctly, 18 Mr. Stanoch. 19 Q. Uh-huh. Do patients have a choice when it 20 comes to the drugs that they are prescribed? 21 MS. LOCKARD: Objection. Speculation. 22 Outside the scope. 23 THE WITNESS: Well, they can certainly 24 talk to their doctors, and FDA encourages that, of 25 course. I would encourage it if I were at FDA. And</p>	<p>Page 254</p> <p>1 by, Doctor. 2 (Whereupon, Exhibit 14 was marked for 3 identification.) 4 BY MR. STANOCHE: 5 Q. This is Exhibit 14. It should be Tab 32 6 in your binder. Tell me when you are there, sir. 7 A. Yes, I see this. Begins, "Expert: 8 Nitrosamines 'Can Slip Through.'" 9 Q. Correct. It's an article in Pharmacy 10 Times from June 29, 2021. Do you see that? 11 A. Yes, I do see it. 12 Q. And it says it includes a discussion with 13 "Edwin Gump, Ph.D., vice president of the Small 14 Modules Department at U.S. Pharmacopeia (USP)." Do 15 you see that? 16 A. Yes, I do see that. 17 Q. Are you familiar with Dr. Gump? 18 A. No, I'm not. 19 Q. Are you familiar with the Small Molecules 20 Department at USP? 21 A. Yes, I think I would -- I am familiar with 22 that. 23 Q. Uh-huh. And then if you want to -- if you 24 would flip to the third page of this document, sir. 25 Tell me when you are there.</p>
<p>Page 255</p> <p>1 I would say, yes, they do have a choice. 2 BY MR. STANOCHE: 3 Q. But they would have no way of knowing, 4 would they, about whether the valsartan they 5 received prior to the recalls contained nitrosamines 6 or not, right? 7 A. Well, I'll make the general statement that 8 I don't think any label for a new drug approved by 9 the NDA or ANDA process has information about 10 impurities on the label. 11 Q. Uh-huh. So then based on the -- 12 valsartan's labeling part of the recalls, there is 13 no way a consumer would be able to make a decision 14 as to whether they wanted a valsartan product that 15 did or did not contain nitrosamines? 16 A. The only way they would know in this 17 particular instance is to read the FDA press 18 releases and talk to their physicians and 19 pharmacists. 20 Q. Right. And prior to those FDA press 21 releases, there was no way for them to know based on 22 the labeling alone? 23 A. Well, I think that's generally true, but 24 I'm not sure entirely. 25 Q. Okay. Let's mark another exhibit. Stand</p>	<p>Page 255</p> <p>1 MS. LOCKARD: You can -- to review it if 2 you need to. 3 THE WITNESS: Yeah, I'm looking at the 4 whole document just a second. It appears to be an 5 interview between a reporter, Alana, and Dr. Gump in 6 a publication for Pharmacy Times. So you want me to 7 go to the third page? One, two, three? 8 BY MR. STANOCHE: 9 Q. Yes. Yep. 10 A. At the top it starts with, "class"? 11 Q. Yes, sir. If you could -- 12 A. Okay. Got it. 13 Q. Great. If you can go on that page down, 14 do you see the bolded name of the reporter, "Alana"; 15 you see that? 16 A. I do see that. 17 Q. Uh-huh. And she asks, "Right. Why are 18 nitrosamines of such particular concern?" You see 19 that? 20 A. Yes, yes. 21 Q. And why don't you read Dr. Gump's response 22 to that question, that first paragraph there, 23 beginning, "So"? 24 A. "So, I'm not a toxicologist, but 25 nitrosamines, from my reading, these are compounds</p>

<p>1 that have been studied for a number of years. 2 There's at least a number of compounds in this class 3 that are known mutagenic carcinogens. So, they're 4 basically fairly nasty cancer-causing actives." 5 Should I stop there? 6 Q. Yes. That's fine. I can ask questions on 7 that. 8 So do you agree with Dr. Gump that 9 nitrosamines are fairly nasty cancer-causing 10 actives? 11 MS. LOCKARD: Objection. Outside the 12 scope of his expert opinion in the 13 class-certification phase. You are asking him 14 causation opinions. 15 THE WITNESS: Well, I guess what I would 16 agree with is Dr. Gump says he is not a 17 toxicologist, and neither am I, so I agree with him 18 there. 19 BY MR. STANOCH: 20 Q. So would you agree with him that 21 nitrosamines are fairly nasty cancer-causing 22 actives? 23 MS. LOCKARD: Objection. Outside the 24 scope of his testimony. Asked and answered. 25 THE WITNESS: You know, I don't agree with</p>	<p>Page 258</p> <p>1 I mean, these are very general statements, but I 2 don't have a particular opinion about them, and they 3 don't relate to my report. 4 Q. Well, respectfully, sir, you are opining 5 on the value received from the drugs that are at 6 issue here. And I'm asking you, then, here if you 7 agree with Dr. Gump from the USP Small Molecule 8 Department about whether people don't really have a 9 choice when it comes to their drugs as opposed to 10 different foodstuffs and other things. 11 A. Is it -- 12 MS. LOCKARD: There is not a question 13 pending. 14 THE WITNESS: I just don't understand the 15 question. I mean, was there a question? Could you 16 rephrase it, perhaps, Mr. Stanoch? 17 BY MR. STANOCH: 18 Q. Do you agree that people can choose not to 19 eat their grilled burger, but people shouldn't have 20 to make a choice or have concerns about the quality 21 of their medicines? 22 MS. LOCKARD: Objection. Vague. Outside 23 the scope of his testimony for class certification. 24 THE WITNESS: And, you know, just 25 continuing on, you know, we can certainly</p>
<p>Page 259</p> <p>1 him there. That seems to be a fairly off-the-cuff 2 comment that would take a very sophisticated expert 3 to speak about the clinical impact of a particular 4 nitrosamine impurity. 5 BY MR. STANOCH: 6 Q. Uh-huh. Then would you agree with 7 Dr. Gump that nitrosamines are compounds that have 8 been studied for a number of years? 9 A. Yes, I think that's true. I would agree 10 with that. 11 Q. Uh-huh. Okay. Then why don't you move to 12 the last paragraph of that same page? It reads, 13 "But the one place." 14 A. "But the one place that people don't 15 really have a choice -- you can choose not to eat 16 that grilled burger -- but people shouldn't have to 17 make a choice" to "have concerns about the quality 18 of their medicines." 19 Q. Right. Do you agree with that statement 20 from Dr. Gump? 21 A. Well, again, these seem kind of very 22 general, unscientific statements. I mean, people 23 shouldn't have to make a -- can choose not to drink 24 your water that has nitrosamines. Does he want to 25 say that, that people should not drink their water?</p>	<p>Page 261</p> <p>1 cherry-pick statements out of this, but on the next 2 page it says, "The U.S. medicines supply is probably 3 the safest, or safe as any in the world, and we want 4 to make sure that the public really feels confident" 5 about "when they need to take a medicine that they 6 can do so and not have other things they have to 7 concern themselves about like nitrosamines." 8 I can certainly agree with that. 9 BY MR. STANOCH: 10 Q. You are agreeing to a different statement 11 that I didn't ask you about; is that what you just 12 did, Doctor? 13 A. Well, you are asking me to read at the 14 bottom of -- maybe I misread where you asked me to 15 read. If so, I apologize. 16 Q. Well, we have been at the same page, 17 Doctor. 18 A. Well, maybe I skipped over a page. Yes, 19 you had me read at the bottom of page 3; is that 20 correct, Mr. Stanoch? 21 Q. Yes, sir. 22 A. Yes, okay. I'm sorry. I jumped ahead. 23 Q. Again, do you agree with Dr. Gump's 24 statement in that paragraph, "But the one place that 25 people don't really have a choice -- you can choose</p>

<p>1 not to eat that grilled burger -- but people 2 shouldn't have to make a choice or have concerns 3 about the quality of their medicines"? 4 MS. LOCKARD: Objection. Vague. Outside 5 the scope of the expert witness report on class 6 certification. 7 THE WITNESS: If you are asking me if I 8 agree with Dr. Gump, I have to say I don't because, 9 you know, the presence of nitrosamine in food and 10 water and foodstuff is very uncertain, and it's 11 certainly not anything I talked about in my report. 12 But I'm not sure people can choose their foods and 13 their water so that they avoid nitrosamines. I just 14 don't know that. 15 Maybe he could make that point with regard 16 to a grilled burger, but what about all the other 17 grilled products and all the other foods that have 18 nitrosamines? It's a very general, if I may say, 19 uninformed statement, so that's why I am hesitating 20 to agree with it. 21 BY MR. STANOCH: 22 Q. So you don't agree? 23 A. I certainly agree that we need to control 24 nitrosamines in our medicines, and that's what this 25 entire effort, which began in 2018, is all about.</p>	<p>Page 262</p> <p>1 knew about nitrosamines until the summer of 2018, 2 right? 3 A. That's what FDA says. I'm not saying 4 that. 5 Q. Uh-huh. Well, you are opining that 6 allegedly the FDA said it was unexpected and nobody 7 knew about it until summer of 2018, right? 8 A. Yes, FDA made a series of statements along 9 those lines. 10 Q. Right. 11 A. And it's definitely a part of my report. 12 Q. It certainly is. I can agree with that. 13 And then once the information came to 14 light about the nitrosamine impurities in valsartan, 15 the regulators in the industry took action, right? 16 A. Well, there was a series of events that 17 now have extended over the past four years and 18 extends to all the chemically synthesized drugs in 19 the country. So I guess you could say it's a very 20 comprehensive set of activities. 21 Q. And if that series of events -- oh, strike 22 that. 23 And if the information about nitrosamine 24 impurities in valsartan came to light earlier, that 25 series of events would have started earlier,</p>
<p>Page 263</p> <p>1 Q. Are you aware of any efforts to control 2 nitrosamines in drug products prior to 2018? 3 A. I am not aware of that, Mr. Stanoch. 4 Q. Uh-huh. Would that be pertinent to the 5 opinions you are offering currently in this case? 6 A. I think it is generally in the sense that 7 science marches on, FDA marches on, drug regulation 8 gets better. We have many, many examples of that in 9 the United States. 10 And is it perfect? Are drugs perfect now? 11 No. But we can hope that in 10 or 20 years they 12 will be better than they are now. And what we see 13 happening here is an example of that happening with 14 regard to valsartan and nitrosamines. 15 Q. So you agree, then, that if information 16 was made known to a API manufacturer prior to the 17 2018 recalls about the potential for nitrosamine 18 impurities, that that should have been something 19 that was dealt with at that time, correct? 20 MS. LOCKARD: Objection. Vague. 21 THE WITNESS: I can't agree with it. It 22 does seem very vague. Perhaps you can restate the 23 question. 24 BY MR. STANOCH: 25 Q. Well, it sounds like you are saying nobody</p>	<p>Page 263</p> <p>1 correct? 2 MS. LOCKARD: Objection. Vague. 3 THE WITNESS: I suppose you could make 4 that hypothetical, and I wouldn't debate you. 5 BY MR. STANOCH: 6 Q. Let's flip to the fourth page of the 7 article in front of you, Doctor. 8 A. One, two, three, four. Okay. Is this the 9 page that starts at the top, "ones that" "need"? 10 Q. Correct, sir. If you can go down to the 11 paragraph where Mr. Gump's name is bolded again, and 12 it begins, "That's a great question." Do you see 13 that? 14 A. Yes, Dr. Gump, "That's a great question." 15 Q. Right. And then can you read the next 16 sentence? 17 A. "So, I think I mentioned that 18 manufacturers have a responsibility to evaluate 19 their processes and their products and look for 20 chance where they could have a risk of 21 nitrosamines." 22 Q. Do you agree with that statement? 23 A. Well, certainly, because Dr. Gump is 24 echoing the FDA guidance that came out well before 25 this interview --</p>

<p>1 Q. Uh-huh.</p> <p>2 A. -- particularly in February 2021, and this 3 is the end of June 2021.</p> <p>4 Q. Uh-huh.</p> <p>5 A. Dr. Gump, if I may say so, is on very safe 6 ground.</p> <p>7 Q. And would --</p> <p>8 (Reporter clarification.)</p> <p>9 THE WITNESS: Safe ground, S-A-F-E.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Would you agree that prior to summer of 12 2018 manufacturers had a responsibility to evaluate 13 their processes and their products to look for the 14 chances of genotoxic impurities?</p> <p>15 MS. LOCKARD: Objection. Outside the 16 scope.</p> <p>17 THE WITNESS: Yes, I think that is what 18 the guidance that we looked at before speaks to, and 19 that had a date -- I guess it was a final date of 20 2018.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. You are referring to the ICH guidance, 23 correct?</p> <p>24 A. Yes, the M7.</p> <p>25 Q. Right. And then there were prior</p>	<p>Page 266</p> <p>1 A. You know, actually, I haven't. I don't 2 write prescriptions.</p> <p>3 Q. Do you know what a pharmacy and 4 therapeutics committee is?</p> <p>5 A. I do.</p> <p>6 Q. Okay. And what is that?</p> <p>7 A. Well, I would say it's a group of experts 8 that build a formulary for a defined benefit offered 9 to a community. So, for example, a hospital, a big 10 hospital in an inner city may have a P&T committee 11 that builds a formulary that the physicians and 12 pharmacists in that community can use to write and 13 dispense drugs -- write prescriptions and dispense 14 drugs.</p> <p>15 Q. We can call that pharmacy and therapeutics 16 committee a P&T committee, right?</p> <p>17 A. Yes, sir.</p> <p>18 Q. Have you ever served on a P&T committee?</p> <p>19 A. No.</p> <p>20 Q. Have you ever consulted with any P&T 21 committee?</p> <p>22 A. Well, I remember during my days at USP I 23 met with the Kaiser P&T committee to discuss how 24 they work, but I wouldn't call that a consultation.</p> <p>25 Q. Okay. The --</p>
<p>Page 267</p> <p>1 iterations of that same guidance, right?</p> <p>2 A. Yes. And other guidances, too, an ICH 3 guidance and, I believe, an EMA guidance.</p> <p>4 Q. Uh-huh. And manufacturers would have 5 responsibilities to evaluate their processes and 6 products for genotoxic impurities under the prior 7 iterations of the ICH and EMA guidance, whatever 8 they may be at that period of time, right?</p> <p>9 A. Yes, and there are certainly other 10 statements in Dr. Gump's interview that we could 11 look to. But I'll wait for your questions, 12 Mr. Stanoch.</p> <p>13 Q. Okay. Very good. So why don't we 14 actually put that aside for now, Doctor.</p> <p>15 Some other questions about your 16 professional experience, sir.</p> <p>17 A. Yes, please.</p> <p>18 Q. You are not a Pharm.D., correct?</p> <p>19 A. I am not.</p> <p>20 Q. Have you ever dispensed a drug?</p> <p>21 A. I have not.</p> <p>22 Q. Have you ever prescribed any valsartan or 23 Diovan?</p> <p>24 A. I have not.</p> <p>25 Q. Have you prescribed any drug since 1990?</p>	<p>Page 269</p> <p>1 A. They weren't asking my opinion. It was 2 more an exchange of information.</p> <p>3 Q. Fair enough. And roughly when was that?</p> <p>4 A. Oh, gee. 2010.</p> <p>5 Q. 2010. Have you ever been asked by any 6 third-party payor to consult on their formulary 7 designs?</p> <p>8 A. No. But I should mention perhaps at this 9 point that USP was asked to consider model 10 guidelines for formularies as part of the Medicare 11 Part D benefit. And that was a large effort for the 12 organization when I was there, and as far as I know, 13 it's still continuing.</p> <p>14 Q. Were you part of that effort while you 15 were working at USP?</p> <p>16 A. Yes, as a matter of fact, I chaired an 17 expert committee which created the first model 18 guidelines, and that was a very interesting effort.</p> <p>19 Q. Uh-huh. And what are the name of the 20 guidelines?</p> <p>21 A. I would call them the USP model guidelines 22 for the Part D -- to assess Part D formulary plans.</p> <p>23 Q. Uh-huh. You are not opining here, Doctor, 24 about what information a P&T committee relies on 25 when making decisions about reimbursements for drug</p>

<p>1 products, correct?</p> <p>2 A. No, I am not.</p> <p>3 Q. All right. Have you ever worked for a</p> <p>4 third-party payor?</p> <p>5 A. I have not.</p> <p>6 Q. Do you know what a PBM is?</p> <p>7 A. It's a pharmacy benefit manager.</p> <p>8 Q. Have you ever worked for a PBM?</p> <p>9 A. No, I have not.</p> <p>10 Q. Have you ever consulted with a PBM</p> <p>11 professionally?</p> <p>12 A. No, I haven't.</p> <p>13 Q. Right. You are not here to opine on</p> <p>14 anything a PBM might rely on when it's making any</p> <p>15 determinations regarding a pharmacy benefit,</p> <p>16 correct?</p> <p>17 A. No. No. I don't believe that's any part</p> <p>18 of my opinions.</p> <p>19 Q. Okay. Let's mark another exhibit. Stand</p> <p>20 by.</p> <p>21 (Whereupon, Exhibit 15 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. This is Exhibit 15. It should be Tab 31</p> <p>25 in your binder, sir. Just let me know when you are</p>	<p>Page 270</p> <p>1 A. Well, wait a minute. I see a third page</p> <p>2 that looked like July 2021. Yes, that could be</p> <p>3 true.</p> <p>4 Q. Right. Well, I guess there is a couple</p> <p>5 things here. First is: Why do some of your</p> <p>6 invoices say ProPharma Group and the other one at</p> <p>7 the end says NDA Partners?</p> <p>8 A. My consulting group, NDA Partners, was</p> <p>9 sold in 2021 to a larger company called Planet</p> <p>10 Pharma, and then Planet Pharma in turn merged with</p> <p>11 ProPharma, so the overarching organization for my</p> <p>12 consulting group, which still exists as NDA</p> <p>13 Partners, is ProPharma Group.</p> <p>14 Q. Got it.</p> <p>15 A. And they do the billing.</p> <p>16 Q. Did anyone at NDA Partners or ProPharma</p> <p>17 Group assist you in the preparation of your report</p> <p>18 that you submitted in this case?</p> <p>19 A. No, not at all.</p> <p>20 Q. Okay. You and you alone wrote your</p> <p>21 report?</p> <p>22 A. Yes, I think that's quite true. I wrote</p> <p>23 this report.</p> <p>24 Q. And the invoice at the end that is on the</p> <p>25 NDA Partners letterhead, it's dated 7/31/2021?</p>
<p>Page 271</p> <p>1 there.</p> <p>2 A. I think it's coming toward me.</p> <p>3 Okay. I see something called ProPharma</p> <p>4 Group.</p> <p>5 Q. Right. And you can look through these</p> <p>6 pages, but this is all of the invoices that were</p> <p>7 produced to us for your work in this case. And if</p> <p>8 you can just look through them and confirm that this</p> <p>9 is the totality of the invoices for your work thus</p> <p>10 far in this case.</p> <p>11 A. ProPharma. I'm a little confused about</p> <p>12 ProPharma Group. Oh, maybe I shouldn't be confused</p> <p>13 about that group. Okay, yes, I see these are my</p> <p>14 invoices, and these invoices should be concurrent</p> <p>15 until the end of January of this year. Okay.</p> <p>16 Q. Right. I mean, the first few pages, I see</p> <p>17 the ProPharma Group, dated 11/30/21. Do you see</p> <p>18 that?</p> <p>19 A. 11/30/2021, yes, I do see that.</p> <p>20 Q. Right. And then the next few pages is for</p> <p>21 work from an invoice dated 12/31/21, right?</p> <p>22 A. Yes, I submit my hours monthly.</p> <p>23 Q. And then the next page after that is an</p> <p>24 invoice for your work through January 31, 2022,</p> <p>25 right?</p>	<p>Page 273</p> <p>1 A. Yeah, I think we may be looking at the</p> <p>2 transition from NDA Partners to ProPharma --</p> <p>3 Q. Uh-huh.</p> <p>4 A. -- so that's an interesting observation.</p> <p>5 Q. And it looks like your first billed work</p> <p>6 in this matter was 7/1/2021, right?</p> <p>7 A. That's when I was first contacted by</p> <p>8 counsel, and then there was a hiatus. I really</p> <p>9 didn't begin substantive work on this report until</p> <p>10 November. You can see that in the invoices.</p> <p>11 And the reason I didn't do any detailed</p> <p>12 work in July until November was because I was not</p> <p>13 involved in the causation discussions.</p> <p>14 Q. Then if you look on the ProPharma Group</p> <p>15 invoice dated 1/31/2022, the first entry is for work</p> <p>16 on January 3rd, 2022, correct?</p> <p>17 A. Wait a minute. I'm having trouble</p> <p>18 catching up with you. But I'm setting aside the</p> <p>19 July one. Now there is one -- I see a July invoice.</p> <p>20 If that's what you are talking about, yes, I see</p> <p>21 that invoice.</p> <p>22 Q. And just to go through this, a few things.</p> <p>23 You say, "Review 82 documents in triplicate." Do</p> <p>24 you see that?</p> <p>25 A. Yes, I do.</p>

<p>1 Q. What do you mean by "in triplicate"?</p> <p>2 A. Well, I'm laughing a little bit because I</p> <p>3 think I got the same folder three times. I had to</p> <p>4 check with counsel many times to make sure that they</p> <p>5 were the same documents in the three folders. So</p> <p>6 that's what that was all about, and I did have a</p> <p>7 good review with counsel about the materials I</p> <p>8 received and where it was all filed.</p> <p>9 Q. Uh-huh. And then further down here, you</p> <p>10 have some entries for, "Read DB deposition," "Read</p> <p>11 EG deposition"; do you see those?</p> <p>12 A. Yes, those refer -- for example, "EG"</p> <p>13 refers to Elizabeth Gray. The "DB" refers, I</p> <p>14 believe, to Daniel Barreto.</p> <p>15 Q. Uh-huh.</p> <p>16 A. And then you can see Panagos expert</p> <p>17 reports.</p> <p>18 Q. Uh-huh. And then that last entry, should</p> <p>19 that be DB deposition as well?</p> <p>20 A. Well, I'm not sure about that. No, I</p> <p>21 think it may be a Binsol deposition.</p> <p>22 Q. Uh-huh. So sometimes you listed the</p> <p>23 specific deposition you read, and sometimes you</p> <p>24 didn't, it looks like; is that right?</p> <p>25 A. I could agree that the way I fill out my</p>	<p>1 A. How can I assist?</p> <p>2 Q. When you say, "Write CBE-30," are you</p> <p>3 referring to sections of your report?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. You weren't writing a CBE-30</p> <p>6 separately outside of your work, right?</p> <p>7 A. Not at all. Oh, no, no, that would not be</p> <p>8 true.</p> <p>9 Q. Uh-huh. And when you say, "Attempt to</p> <p>10 review ANDA files," what does that mean?</p> <p>11 A. Well, ANDA, as you know, the ANDA files</p> <p>12 were very broad and deep and complex. So I would</p> <p>13 say I could review them from a high level, but I</p> <p>14 would not claim that -- I certainly wouldn't claim</p> <p>15 to counsel that I was reviewing the ANDAs in detail.</p> <p>16 Q. Got it. And it looks that throughout all</p> <p>17 of your invoice work, your rate was the same, the</p> <p>18 \$695 an hour?</p> <p>19 A. Yes. And remember, that is what goes to</p> <p>20 the company. That's not what comes to me.</p> <p>21 Q. Uh-huh. What portion do you get?</p> <p>22 A. It's 80 percent.</p> <p>23 Q. Okay. And you don't need a calculator,</p> <p>24 Doctor, unless you want it, but ballpark it looks</p> <p>25 like the invoices for your work to date for this</p>
<p>Page 275</p> <p>1 hours might not be entirely consistent.</p> <p>2 Q. And I'm not going to take issue with that,</p> <p>3 Doctor. I just want to make sure, though, that even</p> <p>4 if you call out specific deposition transcripts here</p> <p>5 in your invoices, is it your position that you did</p> <p>6 review all the deposition transcripts that were in</p> <p>7 your materials considered?</p> <p>8 A. No, I didn't look at all the depositions.</p> <p>9 I selected certain depositions that seemed</p> <p>10 particularly important.</p> <p>11 Q. Which ones, then, did you review?</p> <p>12 A. Well, we can see from this, I would say</p> <p>13 Daniel Barreto, Elizabeth Gray and Mr. Binsol.</p> <p>14 There may have been others, but I might have left</p> <p>15 them out of my invoice.</p> <p>16 Q. Uh-huh. And if you flip back to the -- I</p> <p>17 guess the second page.</p> <p>18 A. I'm trying to stay with you on page</p> <p>19 numbers.</p> <p>20 Q. Well, I guess it -- yeah, I guess it would</p> <p>21 be page 1 of 2.</p> <p>22 A. Is this December?</p> <p>23 Q. Yes. December 31, 2021.</p> <p>24 A. Yes, I'm looking at all that.</p> <p>25 Q. Uh-huh.</p>	<p>Page 277</p> <p>1 matter is approximately \$90,000 or so?</p> <p>2 A. Yes. Let's say 80 percent of that would</p> <p>3 come to me, if we're calculating it that way.</p> <p>4 Q. Understood. All right. You can put those</p> <p>5 aside for now. Thank you.</p> <p>6 Can you pull up your -- I guess it would</p> <p>7 be Exhibit A to your report, sir. I'm looking at</p> <p>8 page 28 of 29 of Exhibit A. It's your prior</p> <p>9 deposition testimony.</p> <p>10 A. Yes, I think it's coming to me. Just a</p> <p>11 second.</p> <p>12 Q. Sure. Let me know when you are there.</p> <p>13 A. Wait a minute. I have it in my CV here.</p> <p>14 (Whereupon, a brief discussion off the</p> <p>15 record.)</p> <p>16 THE WITNESS: I should have it in front of</p> <p>17 me. Hold on just a sec.</p> <p>18 MS. LOCKARD: Here you go.</p> <p>19 THE WITNESS: Oh.</p> <p>20 Okay. I'm with you, Mr. Stanoch. Please</p> <p>21 proceed.</p> <p>22 BY MR. STANOCHE:</p> <p>23 Q. Great. And here you have listed, it looks</p> <p>24 like, 14 matters in the last four years, right?</p> <p>25 A. I'm counting 20, with the most recent</p>

<p style="text-align: right;">Page 278</p> <p>1 being the trial testimony in November 17th. Are you 2 cutting off some because they are not in the last 3 four years?</p> <p>4 Q. Oh, no, I'm sorry. The one I'm looking 5 at -- maybe I have an older version in front of 6 me -- only had 14 numbered entries. Let me look at 7 something else.</p> <p>8 A. It got cut off, but I see 20 in my CV in 9 the final pages. But you may be right if we are 10 just counting the last four years.</p> <p>11 Q. Well, how many numbered matters do you 12 have in the version that you are looking at, Doctor, 13 20?</p> <p>14 A. I have 20, yes.</p> <p>15 Q. Okay. And starting from the top of that, 16 could you -- I just want to know what party you were 17 retained by and in whose behalf you were offering 18 opinions.</p> <p>19 A. Oh, the first one I actually can't 20 remember. I'd have to look it up to tell you.</p> <p>21 The second one was sort of a -- it was 22 a -- I could say it this way. It was a squabble 23 between a lot of people. It really didn't have 24 much -- it didn't have anything to do with FDA, 25 really. And it was an individual where some people</p>	<p style="text-align: right;">Page 280</p> <p>1 Restasis was antitrust. 2 Biogen was -- versus Acorda was related to 3 an FDA guidance where I offered testimony. 4 Stewart, Sandoz was failure to warn. 5 Glumetza was antitrust, and that's still 6 active. 7 Braeburn versus Camurus, that was a 8 company squabble where I was on the side of 9 Braeburn. 10 And then Ranbaxy is still -- I'm sorry. 11 The Glumetza, I think, settled, and the Ranbaxy is 12 still in progress, but it's antitrust. I'm on the 13 side of the plaintiffs. 14 Genentech versus InterMune was patent. I 15 was on the side of InterMune, the pioneer. 16 Mallinckrodt versus debtors, that was a 17 squabble between third-party payors, if you will, 18 and Mallinckrodt, and I was on the Mallinckrodt 19 side. 20 Is that helpful, Mr. Stanoch? 21 Q. No, it is. I appreciate you going through 22 that. 23 And, Doctor, for the prior cases you have 24 offered expert opinions in, for those that are class 25 actions, is it fair to say you have always been</p>
<p style="text-align: right;">Page 279</p> <p>1 were complaining that he had taken intellectual 2 property from a firm.</p> <p>3 Supernus versus Actavis I think was a 4 patent issue, and I was on the Supernus side.</p> <p>5 The fourth one I think was antitrust.</p> <p>6 The fifth one was a debate about a generic 7 company versus Shire, and I was on the Shire side.</p> <p>8 Solodyn was antitrust. I was on the part 9 of plaintiffs.</p> <p>10 Loestrin I think was antitrust, and that 11 was on the part of plaintiffs.</p> <p>12 Arbor versus ANI was sort of a company 13 squabble, and I was on the ANI side.</p> <p>14 Fresenius Kabi and Par was an argument 15 about -- I'm summarizing very briefly, but I think 16 it was restraint of trade, and I was on the Par 17 side. They were the defendants, as I recall.</p> <p>18 Galderma versus Teva was patent, and I was 19 on the Teva side as the -- I'm struggling with what 20 they were. Yeah, they got sued, so they were the 21 defendant.</p> <p>22 Belcher versus Hospira. I don't remember 23 that one. I'd have to look it up. I apologize.</p> <p>24 Continuing, Vision versus Sunrise, that 25 was a sort of company squabble over GMPs.</p>	<p style="text-align: right;">Page 281</p> <p>1 retained by a defendant in those actions?</p> <p>2 A. You know, I'm not sure that I would 3 identify any of those as class actions. I have to 4 say I'm a little uncertain about just what a class 5 action is, and so I couldn't say I was on one side 6 or the other.</p> <p>7 If you say an antitrust is a class action, 8 I think I would agree with you that I'm usually on 9 the side of plaintiffs, but I have one now where I 10 believe it's antitrust and I'm on the side of the 11 pioneer --</p> <p>12 Q. But you just said --</p> <p>13 A. -- so I don't think I can agree with you 14 that I'm always on one side versus another.</p> <p>15 Q. Uh-huh. But you are on the side of the 16 defendants now in this case, right?</p> <p>17 A. Yes.</p> <p>18 Q. All right. And, the extent you remember, 19 just go through and tell me where you think you were 20 on the side of the defendants in your list of cases.</p> <p>21 A. Oh, dear. Well, I'll give some examples. 22 I think Mallinckrodt was the defendant. They were 23 getting -- in Genentech I was on the side of the 24 plaintiff.</p> <p>25 Ranbaxy, I was on the side of plaintiff.</p>

<p>1 during the latter half of my service. In the first 2 half I was stationed in Seoul, Korea. 3 When I finished that service, I entered a 4 clinical pharmacology fellowship at the University 5 of California, San Francisco. That lasted three 6 years. And based on my training, I was able to 7 obtain Board certification in both internal medicine 8 and clinical pharmacology. 9 Q. Were you an officer in the Army? 10 A. Yes, I was a major. 11 Q. What licenses have you held? 12 A. I was licensed to practice medicine in 13 California, but I didn't continue that or my Board 14 certifications when I came to FDA in 1990 because it 15 was a full-time job at FDA and I was not practicing 16 clinical medicine. 17 Q. Have you held any licenses in 18 pharmacology? 19 A. Clinical pharmacology. There is no 20 licensure, but I was Board-certified in clinical 21 pharmacology. 22 Q. What did you do when you left private 23 practice or -- as a medical doctor? 24 MR. STANOCH: Objection to form. 25 Go ahead.</p>	<p>Page 286</p> <p>1 the level of the center, where I held multiple 2 positions, but I ended my career and the last 3 several years of my time at FDA working as a deputy 4 director for the center director, who was Dr. Janet 5 Woodcock at the time. Dr. Woodcock is now the 6 commissioner of FDA on an acting basis. 7 And in my role as deputy center director, 8 I had a lot of responsibilities, but I was 9 principally the director of the Office of 10 Pharmaceutical Science. That office is now the 11 Office of Pharmaceutical Quality at FDA. And I had 12 oversight for the Office of Generic Drugs, the 13 Office of Clinical Pharmacology and Biopharmaceutics 14 and the Office of Testing and Research and also the 15 Office of Chemistry. So I had a terrific experience 16 overseeing about four or five of the disciplines 17 that contribute to the review of an NDA, as well as 18 oversight for the Office of Generic Drugs and many 19 other responsibilities. 20 I then left FDA in 2000. I became chief 21 executive officer and chair of the Council of 22 Experts. And I would say over my 14-year period 23 there was a rapid expansion of USP, a globalization 24 of our activities, a focus on the science of 25 metrology, which I think is the undergirding science</p>
<p>Page 287</p> <p>1 THE WITNESS: I would say I was never in 2 private practice. I worked at the University of 3 California, San Francisco, doing clinical 4 investigations for NDA and ANDA sponsors. And it 5 was there that I built a focus on bioavailability 6 and bioequivalence that I think has continued 7 throughout my career. 8 I spent a year after my service at UCSF in 9 a small company in South San Francisco that was 10 studying an HIV medicine. 11 And then Dr. Carl Peck, who has been a 12 very good mentor and friend, brought me to FDA in 13 1990 to head up the Office of Generic Drugs. And 14 for those who may remember, that was a difficult 15 time for both the generic industry and FDA. It had 16 to do with something that briefly is called the 17 generic drug scandal. 18 But I was very pleased to work in the 19 Office of Generic Drugs. We worked with Congress 20 and with industry to sort of straighten it all out. 21 And I think we did get it straightened out. We sort 22 of put it back on a solid footing. And the office 23 has zoomed, if you will, ever since then over the 24 ensuing decades. 25 In 1993, Dr. Peck left, so I came up to</p>	<p>Page 289</p> <p>1 for what USP does, and the addition of a lot of 2 compendia. 3 USP started out, when I was there, with 4 USP-NF. Those are official compendia of the United 5 States. But we added Food Chemical Codex, a Dietary 6 Supplement Compendium. We even experimented with a 7 novel compendium that we called the Medicines 8 Compendium. 9 And overall it was a very remarkable 10 experience, and I am forever grateful for having 11 that experience. 12 Q. What -- 13 A. After leaving USP, I became a consultant 14 at the invitation of Dr. Peck again. Dr. Peck has 15 been a great mentor, and he was the center director 16 who brought me to FDA. And I have continued doing 17 consulting in his consulting group, called NDA 18 Partners, as we have discussed, and over the last 19 several years I've focused primarily on litigation. 20 Q. How many years were you at the FDA, 21 Dr. Williams? 22 MR. STANOCH: Objection to the form. 23 THE WITNESS: Ten. 24 BY MS. LOCKARD: 25 Q. How many years were you at the United</p>

<p>1 States Pharmacopeial Convention, the USP?</p> <p>2 A. Fourteen.</p> <p>3 MR. STANOCH: Same objection.</p> <p>4 BY MS. LOCKARD:</p> <p>5 Q. What year did you leave the USP?</p> <p>6 A. It was the beginning of 2014.</p> <p>7 Q. And your CV that was marked as Exhibit 16, 8 I was following along, but it has the dates and 9 specific responsibilities and titles for your 10 positions at FDA, USP and otherwise. Is that still 11 accurate?</p> <p>12 A. Yes, no changes.</p> <p>13 Q. There are a number of honors and awards 14 listed here in your CV. Are those still active?</p> <p>15 MR. STANOCH: Objection.</p> <p>16 THE WITNESS: Yes, no changes.</p> <p>17 (Reporter clarification.)</p> <p>18 THE WITNESS: No changes in those honors 19 and awards.</p> <p>20 BY MS. LOCKARD:</p> <p>21 Q. Have there been any changes in your board 22 memberships or research awards listed on your CV?</p> <p>23 A. No, none. And I would say in my quasi 24 retirement that's all been -- it's been replaced, if 25 you will, by the litigation efforts.</p>	<p>Page 290</p> <p>1 many journal articles you have contributed to?</p> <p>2 A. Well, if you add all my publications, 3 including the USP publications, I think we're well 4 over 200.</p> <p>5 Q. Have you participated in writing any books 6 or book chapters?</p> <p>7 A. Yes, I have done that.</p> <p>8 Q. How many of those?</p> <p>9 A. I think you would have to look at the CV, 10 but I'm sure we're in the scores, maybe, or between 11 10 and 20.</p> <p>12 Q. And are those journal articles and book 13 chapters all listed on your CV, Dr. Williams?</p> <p>14 A. Yes, I think the CV is complete.</p> <p>15 Q. Oh, I would like to attach as Exhibit 18 a 16 complete copy of your set of materials that we sent 17 for your consideration. And we have been handed a 18 thumb drive of that which we can get to the court 19 reporter.</p> <p>20 (Whereupon, Exhibit 18 was marked for 21 identification.)</p> <p>22 MS. LOCKARD: Exhibit 18, for the record, 23 is going to be Dr. Williams' file.</p> <p>24 MR. STANOCH: Counsel, this is everything 25 listed in the -- what do you call it, the materials</p>
<p>Page 291</p> <p>1 Q. Have you done any teaching work?</p> <p>2 MR. STANOCH: Objection.</p> <p>3 THE WITNESS: Yes, I would say at UCSF I 4 taught pharmacy and medical students and also worked 5 with graduate students on their Ph.D.s.</p> <p>6 BY MS. LOCKARD:</p> <p>7 Q. Have you served on any editorial boards?</p> <p>8 MR. STANOCH: Objection.</p> <p>9 THE WITNESS: I have been a reviewer for 10 multiple journals and --</p> <p>11 BY MS. LOCKARD:</p> <p>12 Q. Any that would be relevant to this 13 litigation?</p> <p>14 MR. STANOCH: Uh-huh. A standing 15 objection to background.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: Well, yes, I think all of my 18 writings and research in one way or another relate 19 to what we're talking about here in this, the 20 quality of medicines, therapeutic equivalence, 21 substitution, metrology, measurements. I feel 22 everything in my wheelhouse, if you will, is related 23 to this litigation.</p> <p>24 BY MS. LOCKARD:</p> <p>25 Q. Do you have any estimates in terms of how</p>	<p>Page 293</p> <p>1 considered, Exhibit 2?</p> <p>2 MS. LOCKARD: That's correct.</p> <p>3 MR. HARKINS: Yes, yeah.</p> <p>4 MS. LOCKARD: Yes.</p> <p>5 MR. STANOCH: Okay.</p> <p>6 MR. HARKINS: Also including the copy of 7 the revised list of materials considered that was 8 submitted with the production of those materials two 9 days ago.</p> <p>10 (Whereupon, a brief discussion off the 11 record.)</p> <p>12 BY MS. LOCKARD:</p> <p>13 Q. All right. Dr. Williams, you were asked 14 about a document we reviewed earlier today on a 15 break that was identified as Exhibit 3, and it was 16 the GNTM e-mail. Do you recall being asked about 17 that?</p> <p>18 A. I do recall.</p> <p>19 Q. And did that document refresh your 20 recollection about how Teva learned of the 21 nitrosamine issue initially?</p> <p>22 MR. STANOCH: Objection to form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. STANOCH: Asked and answered.</p> <p>25 Go ahead.</p>

<p>1 THE WITNESS: Yes. This is definitely a 2 document I cited. It was very important to my 3 opinions.</p> <p>4 And it has a huge distribution list, GNTM, 5 global notice to management, where Teva is 6 communicating to its scores of sites across the 7 globe.</p> <p>8 And it starts -- it's an incident 9 category, foreign matter, and it says, "On 10 June 20th, 2018, vendor" ZHP "notified Teva that 11 they came to be aware of a previously unknown 12 impurity that may have genotoxic potential."</p> <p>13 BY MS. LOCKARD:</p> <p>14 Q. But let me stop you there and ask: So 15 does that clarify for you how Teva learned of the 16 potential --</p> <p>17 A. Yes.</p> <p>18 Q. -- impurity?</p> <p>19 A. Yes.</p> <p>20 MR. STANOCH: Objection.</p> <p>21 THE WITNESS: And then it --</p> <p>22 BY MS. LOCKARD:</p> <p>23 Q. Okay. And the next question is: On that 24 date of the initial notification, is there anything 25 there that indicates what the potential impurity</p>	<p>Page 294</p> <p>1 THE WITNESS: No, I would say it is not.</p> <p>2 BY MS. LOCKARD:</p> <p>3 Q. You were asked some questions about 4 Novartis and testing they allegedly did on some of 5 their products. Do you recall that?</p> <p>6 A. I do.</p> <p>7 Q. Do you have any information about 8 Novartis' testing of their Diovan or any other 9 products with respect to nitrosamines?</p> <p>10 A. No, I don't recall seeing any information, 11 and it was not pertinent to my report.</p> <p>12 Q. Do you know why Novartis was testing or 13 what they were testing, if at all?</p> <p>14 A. No, I really don't. I have no information 15 about it that I remember.</p> <p>16 Q. -- Novartis testing relevant to any of the 17 opinions you have given to date in this case?</p> <p>18 MR. STANOCH: Objection.</p> <p>19 THE WITNESS: It is not.</p> <p>20 BY MS. LOCKARD:</p> <p>21 Q. You were asked some questions about the 22 limits of the nitrosamine, either interim limits or 23 permanent limits, by FDA. Are you offering any 24 opinions about whether those limits were 25 appropriate?</p>
<p>1 was?</p> <p>2 A. I don't see that here. I may be missing 3 it, but I don't see that it states the impurity.</p> <p>4 Q. You can put that aside for the moment.</p> <p>5 Are 483s a final agency determination?</p> <p>6 A. No. I would say they are a set of 7 observations from an Office of Regulatory inspector, 8 typically, who is visiting a manufacturing site and 9 writing observations over a several-day period, 10 either in the United States or overseas.</p> <p>11 Q. Are warning letters a final agency 12 determination?</p> <p>13 A. The way I would say it is the warning 14 letter is an escalation of FDA's concern. I 15 sometimes say it's kind of a shot across the bow of 16 a company, that they better pay closer attention to 17 what FDA is saying and do something.</p> <p>18 But even there, the company is allowed to 19 respond, allowed to resolve issues and ultimately 20 allowed to have their manufacturing site cleared of 21 the issues and the inspection closed out by FDA 22 satisfactorily.</p> <p>23 Q. So then is a warning letter necessarily a 24 final determination by FDA?</p> <p>25 MR. STANOCH: Objection to form.</p>	<p>Page 295</p> <p>1 A. No, I am not.</p> <p>2 Q. Have you endeavored to render any opinions 3 about the testing methodology employed to detect 4 limits of nitrosamines?</p> <p>5 A. No, it's not part of my opinion, although 6 I mention it in my report.</p> <p>7 Q. Do you have any opinions in this case 8 about whether nitrosamines are or are not 9 carcinogenic?</p> <p>10 MR. STANOCH: Objection to form.</p> <p>11 THE WITNESS: No, I'm not offering any 12 opinion that speaks to pharmacology/toxicology of 13 the nitrosamines.</p> <p>14 BY MS. LOCKARD:</p> <p>15 Q. Do you intend to offer any opinions about 16 whether nitrosamines in the Teva products were a 17 potential human carcinogen?</p> <p>18 MR. STANOCH: Objection to form.</p> <p>19 THE WITNESS: No, I don't offer that 20 either.</p> <p>21 BY MS. LOCKARD:</p> <p>22 Q. Counsel made the point earlier today that 23 even if the USP does not provide for testing of 24 nitrosamines, that a manufacturer can still 25 institute its own testing for nitrosamine.</p>

<p>1 MR. STANOCH: Objection. There's no 2 question.</p> <p>3 THE WITNESS: That's absolutely true. A 4 manufacturer can build additional testing into its 5 private specification working with FDA.</p> <p>6 BY MS. LOCKARD:</p> <p>7 Q. Well, in order for a company to initiate 8 testing of a genotoxic impurity, what do they need 9 to know?</p> <p>10 A. Well, that relates to something FDA said 11 in some of their public announcements. You have to 12 suspect that it's there. You wouldn't test for it 13 if you didn't think it was there, so you first have 14 to have a suspicion that it's there. And then I 15 would say you would have to see some identifiable 16 peak on a chromatogram that raises your concern, and 17 that would lead into an understanding of looking at 18 the impurity and assessing its genotoxic potential.</p> <p>19 Q. Did you in this case endeavor to do an 20 independent assessment, at this stage of the case, 21 whether Teva violated any cGMPs?</p> <p>22 MR. STANOCH: Objection to form.</p> <p>23 THE WITNESS: The only thing I did was 24 look at FDA's record of inspections of Teva's GMPs 25 at its Malta and Jerusalem sites, but I didn't do</p>	<p>Page 298</p> <p>1 BY MS. LOCKARD:</p> <p>2 Q. Do you understand that at some point we 3 may ask you to review additional materials and 4 render liability opinions?</p> <p>5 A. Yes, I understand that may come later on, 6 but it is not happening now.</p> <p>7 Q. Are you willing to do that if so asked?</p> <p>8 A. Yes.</p> <p>9 Q. Are you qualified to do so at certain 10 elements if so asked?</p> <p>11 MR. STANOCH: Objection. Form.</p> <p>12 THE WITNESS: I believe so.</p> <p>13 BY MS. LOCKARD:</p> <p>14 Q. You were asked some questions about what 15 do plaintiffs or patients expect; do you remember 16 that?</p> <p>17 A. I do remember that.</p> <p>18 Q. Do you intend to offer any opinions about 19 plaintiffs' expectations in this case?</p> <p>20 MR. STANOCH: Objection to form.</p> <p>21 THE WITNESS: No, I mean, I tried to 22 answer those questions as best I could, but they 23 were not part of my report and not part of my 24 opinions.</p> <p>25</p>
<p>Page 299</p> <p>1 any independent evaluation of Teva's GMP adherence.</p> <p>2 BY MS. LOCKARD:</p> <p>3 Q. Have you endeavored to do any independent 4 assessment of Teva's compliance with any of its 5 policies or procedures?</p> <p>6 A. No, not at all. That was not part of my 7 report, and then I didn't cite to any documents to 8 that point.</p> <p>9 Q. Now, you were asked about the purpose of 10 your report, and you have heard a lot of objections 11 today about the class-certification opinions that 12 you rendered in your report. Do you have an 13 understanding that you have not been asked by me or 14 my firm to provide any liability opinions at this 15 point in time?</p> <p>16 MR. STANOCH: Objection to form.</p> <p>17 THE WITNESS: I do understand that.</p> <p>18 BY MS. LOCKARD:</p> <p>19 Q. Have you intended to give liability 20 opinions today?</p> <p>21 A. No.</p> <p>22 MR. STANOCH: Objection. Form.</p> <p>23 THE WITNESS: I have tried not to give 24 liability opinions.</p> <p>25</p>	<p>Page 301</p> <p>1 BY MS. LOCKARD:</p> <p>2 Q. Do you intend to offer any opinions about 3 various choices available to plaintiffs who were 4 prescribed hypertension medications; is that what --</p> <p>5 MR. STANOCH: Objection to form.</p> <p>6 BY MS. LOCKARD:</p> <p>7 Q. -- hired to do?</p> <p>8 MR. STANOCH: Sorry. Sorry, Counsel. 9 Objection to form.</p> <p>10 THE WITNESS: No, I -- (Reporter clarification.)</p> <p>11 MR. STANOCH: I apologize. I was just 12 objecting. I'm sorry, Victoria.</p> <p>13 THE REPORTER: Okay. So sorry.</p> <p>14 BY MS. LOCKARD:</p> <p>15 Q. I think I said, is that what you were 16 hired to do?</p> <p>17 A. No.</p> <p>18 Q. And recognizing you have a medical degree, 19 but do you prescribe, consult, discuss with patients 20 hypertension medications?</p> <p>21 A. No, not at all. I am not a practicing 22 clinical doctor.</p> <p>23 Q. You were also asked to discuss some issues 24 with respect to recycled solvents in the API that</p>

<p>1 Teva was supplied. Do you recall that?</p> <p>2 A. I do.</p> <p>3 Q. And are you familiar with recycled</p> <p>4 solvents being used in pharmaceutical manufacturing?</p> <p>5 A. You know, actually I'm not. The first</p> <p>6 time I read about it was when I started reading</p> <p>7 materials for this report.</p> <p>8 Q. Is it something that you would ordinarily</p> <p>9 be involved in, in terms of your role at USP or FDA,</p> <p>10 to investigate recycled solvents?</p> <p>11 MR. STANOCH: Objection to form.</p> <p>12 THE WITNESS: No. No, really not. To me</p> <p>13 it seems more like a GMP issue, and I don't speak as</p> <p>14 a GMP expert.</p> <p>15 (Whereupon, a brief discussion off the</p> <p>16 record.)</p> <p>17 BY MS. LOCKARD:</p> <p>18 Q. So you don't -- bless you.</p> <p>19 You don't intend to offer any opinions in</p> <p>20 this case criticizing the use of recycled solvents,</p> <p>21 do you?</p> <p>22 MR. STANOCH: Objection.</p> <p>23 THE WITNESS: No. As far as I can</p> <p>24 remember from my report, I don't speak at all to</p> <p>25 recycled solvents, although FDA speaks about that in</p>	<p>Page 302</p> <p>1 A. No. And my understanding is that a</p> <p>2 quality agreement is not pertinent to the purchase</p> <p>3 of a drug substance from a manufacturer by a</p> <p>4 drug-product manufacturer.</p> <p>5 Q. You were asked about Teva's submission of</p> <p>6 their CBE-30 --</p> <p>7 A. Yes.</p> <p>8 Q. -- for the change in ZHP supply of API; do</p> <p>9 you recall that?</p> <p>10 A. I do recall that.</p> <p>11 Q. Based on your experience, do you have any</p> <p>12 concerns with the use of the CBE-30 to convey those</p> <p>13 changes to FDA by Teva?</p> <p>14 MR. STANOCH: Objection.</p> <p>15 THE WITNESS: No, I think Teva, Watson at</p> <p>16 the time, was following FDA guidance, and if FDA had</p> <p>17 any concerns, they could certainly have communicated</p> <p>18 that to Teva right away. And they could have asked</p> <p>19 Teva to wait and they could have converted it to a</p> <p>20 postapproval supplement.</p> <p>21 BY MS. LOCKARD:</p> <p>22 Q. Did they do that?</p> <p>23 A. They did not. In fact, in both instances,</p> <p>24 they approved very rapidly the CBE-30, within days</p> <p>25 of its submission.</p>
<p>Page 303</p> <p>1 their guidance as a source of nitrosamine</p> <p>2 impurities.</p> <p>3 BY MS. LOCKARD:</p> <p>4 Q. Which guidance are you referring to?</p> <p>5 A. The 2021 nitrosamine impurities guidance.</p> <p>6 Q. You aren't aware of any FDA guidance in</p> <p>7 2018 or prior that identified recycled solvents as a</p> <p>8 source of impurities, are you?</p> <p>9 A. No. And to me --</p> <p>10 MR. STANOCH: Objection.</p> <p>11 THE WITNESS: Oh, I'm sorry.</p> <p>12 To me it's an example of how FDA and</p> <p>13 industry learned a great deal from this experience</p> <p>14 beginning in 2018.</p> <p>15 BY MS. LOCKARD:</p> <p>16 Q. Ultimately, is it important to your review</p> <p>17 and opinions whether Mylan was using recycled</p> <p>18 solvents or not in the API it supplied Teva?</p> <p>19 MR. STANOCH: Objection.</p> <p>20 THE WITNESS: No, to me it doesn't impact</p> <p>21 my report one way or the other.</p> <p>22 BY MS. LOCKARD:</p> <p>23 Q. Does the presence or absence of a quality</p> <p>24 agreement with Mylan and Teva impact your opinions</p> <p>25 in your report in any way?</p>	<p>Page 304</p> <p>1 Q. You were shown a press release about</p> <p>2 Ranbaxy and a negotiated guilty plea they entered</p> <p>3 with respect to their products; do you remember</p> <p>4 that?</p> <p>5 A. I do see it. As a matter of fact, it's</p> <p>6 still on my screen. I'm looking at it to my right.</p> <p>7 Q. And you have read through this document,</p> <p>8 or to some extent; is that correct?</p> <p>9 A. I have an understanding of what it's</p> <p>10 saying.</p> <p>11 Q. And to the extent that the document itself</p> <p>12 and the negotiated plea deal suggests that there was</p> <p>13 some retrospective determination that Ranbaxy</p> <p>14 products were determined to be adulterated, is that</p> <p>15 analogous in any way to the situation with Teva's</p> <p>16 products?</p> <p>17 MR. STANOCH: Objection to form.</p> <p>18 THE WITNESS: This entire matter with</p> <p>19 Ranbaxy, to me, it is a completely different set of</p> <p>20 circumstances.</p> <p>21 First of all, it involves the Department</p> <p>22 of Justice. It has a huge civil penalty. It</p> <p>23 involves fraud and false statements to the agency.</p> <p>24 It certainly involves GMP violations.</p> <p>25 And what happens when you see an</p>

<p style="text-align: right;">Page 306</p> <p>1 announcement like this, you are seeing the result of 2 years of effort on the part of FDA and the 3 Department of Justice to have Ranbaxy agree to a set 4 of statements, including the statement about 5 adulteration in the prior years.</p> <p>6 So I would say it has no relationship at 7 all to my current report or my opinions.</p> <p>8 BY MS. LOCKARD:</p> <p>9 Q. So in the Ranbaxy situation, was the 10 language that was referenced about adulteration, to 11 your knowledge, was that the product of negotiation 12 between Ranbaxy --</p> <p>13 MR. STANOCH: Objection to the -- 14 (Reporter clarification.)</p> <p>15 BY MS. LOCKARD:</p> <p>16 Q. Government?</p> <p>17 THE REPORTER: Thank you.</p> <p>18 MR. STANOCH: Objection. Objection.</p> <p>19 THE WITNESS: Well, to the extent I know 20 what happened here, and I know it was a very 21 detailed effort on the part of the agency, yes, it 22 was a negotiated settlement where Ranbaxy and FDA 23 and the Department of Justice are agreeing to the 24 statement that appears on my screen.</p> <p>25</p>	<p style="text-align: right;">Page 308</p> <p>1 BY MS. LOCKARD:</p> <p>2 Q. The confidentiality of DMFs was discussed 3 earlier today. Do you remember that?</p> <p>4 A. I do.</p> <p>5 Q. Is there any part of the DMF that FDA 6 actually considers to be open?</p> <p>7 A. If we look at some of the documents I 8 cited, you will see that FDA considers the DMF 9 entirely confidential. In Europe sometimes they 10 talk about an open part or a closed part, but FDA 11 thinks of it as all closed, all confidential.</p> <p>12 Q. You had said that theoretically you 13 suppose companies could decide on their own to 14 share, but are you familiar with that happening in 15 this case?</p> <p>16 MR. STANOCH: Objection.</p> <p>17 THE WITNESS: I'm not, and it seems 18 unusual. It seems to undercut the purpose of the 19 DMF, which is to keep some parts of it confidential.</p> <p>20 What the buyer, in this case the ANDA 21 holder, would see is the certificate of analysis, 22 which is the specification you use to test the drug 23 substance, and that's all they would see.</p> <p>24 BY MS. LOCKARD:</p> <p>25 Q. And in this situation, would you expect</p>
<p style="text-align: right;">Page 307</p> <p>1 BY MS. LOCKARD:</p> <p>2 Q. To your knowledge, has Teva been involved 3 in any DOJ investigation, criminal proceeding, FDA 4 fines, like that described in the Ranbaxy press 5 release with respect to its --</p> <p>6 A. No, I have not --</p> <p>7 (Whereupon, a brief discussion off the 8 record.)</p> <p>9 BY MS. LOCKARD:</p> <p>10 Q. Okay. My question to you, Dr. Williams, 11 was: To your knowledge, has Teva been involved in 12 any DOJ investigation, criminal proceeding, FDA 13 fines or fraud with respect to its valsartan like 14 that that was described in this Ranbaxy press 15 release that you were provided today?</p> <p>16 MR. STANOCH: Objection.</p> <p>17 THE WITNESS: Not at all.</p> <p>18 BY MS. LOCKARD:</p> <p>19 Q. Does this Ranbaxy press release and the 20 findings in any way undercut your opinions that you 21 have rendered in this case about Teva's valsartan 22 not being adulterated?</p> <p>23 MR. STANOCH: Objection.</p> <p>24 THE WITNESS: No, not at all.</p> <p>25</p>	<p style="text-align: right;">Page 309</p> <p>1 Teva and its API suppliers to share the DMF or 2 supply Teva with anything other than the certificate 3 of analyses?</p> <p>4 MR. STANOCH: Objection to form.</p> <p>5 THE WITNESS: I didn't see any documents 6 otherwise, so my belief is that the two 7 drug-substance manufacturers were keeping their DMF 8 confidential, as is typical of the way DMFs are 9 handled.</p> <p>10 BY MS. LOCKARD:</p> <p>11 Q. Right. So is it surprising to you if you 12 learn that the companies in this case didn't -- did 13 not share the DMF portion?</p> <p>14 A. That would not be surprising.</p> <p>15 MR. STANOCH: Objection.</p> <p>16 THE WITNESS: That would not be 17 surprising. That would be typical.</p> <p>18 BY MS. LOCKARD:</p> <p>19 Q. Now, you were asked a line of questions 20 referencing back to your report, and it was under 21 "The FDA Drug Approval Process" section in your 22 report. You were asked about a line that said, "A 23 recall is a voluntary action taken by a company to 24 remove a defective drug product from the market."</p> <p>25 Do you recall that?</p>

<p>1 MR. STANOCH: Objection.</p> <p>2 THE WITNESS: I do recall that.</p> <p>3 BY MS. LOCKARD:</p> <p>4 Q. And had you taken that as a quote from an</p> <p>5 FDA general statement about drug recalls?</p> <p>6 MR. STANOCH: Objection.</p> <p>7 THE WITNESS: I think if we look at the</p> <p>8 FDA website and see what it says about recalls, that</p> <p>9 is what it says. That's the terminology they use.</p> <p>10 BY MS. LOCKARD:</p> <p>11 Q. Can a recall occur for reasons other than</p> <p>12 a defective product?</p> <p>13 MR. STANOCH: Objection.</p> <p>14 THE WITNESS: Well, I would say this is an</p> <p>15 interesting example, because at the time Teva and</p> <p>16 FDA agreed to recall their valsartan products, there</p> <p>17 was no understanding the products were defective.</p> <p>18 They were not defective. FDA had not set limits on</p> <p>19 nitrosamine impurities. But still FDA and Teva</p> <p>20 agreed that they should come off the market because</p> <p>21 of the presence of the nitrosamine impurities.</p> <p>22 Later on, when FDA set limits, you could</p> <p>23 say, well, they might have been considered</p> <p>24 adulterated, but in the summer of 2018, with regard</p> <p>25 to the ZHP drug substance, I do not see them as</p>	<p>Page 310</p> <p>1 Q. Let's see, actually.</p> <p>2 A. Oh.</p> <p>3 Q. Pull that out of my --</p> <p>4 A. Oh.</p> <p>5 Q. It's there.</p> <p>6 A. Yes. I see it, thank you.</p> <p>7 Q. Are you familiar with the Pharmacy Times?</p> <p>8 A. Yes, somewhat.</p> <p>9 Q. Have you ever seen this article before</p> <p>10 today?</p> <p>11 A. No, I have not.</p> <p>12 Q. Do you see what the date on this article</p> <p>13 was?</p> <p>14 A. June 29th, 2021.</p> <p>15 Q. Are you familiar with Edwin Gump?</p> <p>16 A. I actually am not.</p> <p>17 Q. Are you familiar with the Small Molecules</p> <p>18 Department at U.S. Pharmacopeia, USP?</p> <p>19 A. Yes.</p> <p>20 MR. STANOCH: Objection. Form.</p> <p>21 THE WITNESS: I would say I helped create</p> <p>22 that department when I first came to USP in 2000.</p> <p>23 BY MS. LOCKARD:</p> <p>24 Q. There is also a reference on the second</p> <p>25 page to the USP Nitrosamines Joint Subcommittee.</p>
<p>Page 311</p> <p>1 being defective products.</p> <p>2 BY MS. LOCKARD:</p> <p>3 Q. So just to be clear, do you hold any</p> <p>4 opinion that the valsartan products that were sold</p> <p>5 to customers by Teva were sold in a defective state?</p> <p>6 MR. STANOCH: Objection to form.</p> <p>7 THE WITNESS: I wouldn't use those words,</p> <p>8 and that is not part of my opinion.</p> <p>9 BY MS. LOCKARD:</p> <p>10 Q. Does the presence -- does the sheer</p> <p>11 presence of any nitrosamine render a product</p> <p>12 defective?</p> <p>13 MR. STANOCH: Objection to form.</p> <p>14 THE WITNESS: No. I would say,</p> <p>15 particularly if we look at the nitrosamine guidance,</p> <p>16 FDA will allow nitrosamine impurities in ingredients</p> <p>17 and products as long as they stay within acceptable</p> <p>18 intake limits.</p> <p>19 BY MS. LOCKARD:</p> <p>20 Q. So is it your opinion that if a drug</p> <p>21 product is sold -- well, strike that.</p> <p>22 You were asked about Exhibit 14. See if</p> <p>23 we can get a copy of that for you. It was an</p> <p>24 interview in the Pharmacy Times.</p> <p>25 A. I don't think I have that.</p>	<p>Page 313</p> <p>1 Was that a subcommittee in effect at FDA when you</p> <p>2 were there?</p> <p>3 A. No, it was not.</p> <p>4 Q. When was that formed, if you know?</p> <p>5 A. I actually don't know, and I'm not sure I</p> <p>6 see where you are reading. Could you help me,</p> <p>7 Ms. Lockard?</p> <p>8 Q. If you are looking at the bottom of what</p> <p>9 is page 2. Are you with me there?</p> <p>10 A. Actually, I am still not. There is</p> <p>11 something where it speaks to a subcommittee of an</p> <p>12 expert committee?</p> <p>13 Q. Yeah, it is the very end of page 2, where</p> <p>14 it says "Alana Hippenstein," she says, "That's</p> <p>15 fascinating."</p> <p>16 A. Oh.</p> <p>17 Q. "What is the USP Nitrosamines Joint</p> <p>18 Subcommittee" --</p> <p>19 A. Yes, I see.</p> <p>20 Q. -- "and why was it established?" Do you</p> <p>21 see that?</p> <p>22 A. Yes, I can, you know, understand, I think,</p> <p>23 what that subcommittee was doing and how it was</p> <p>24 formed.</p> <p>25 Q. Okay. Can you explain briefly your</p>

<p style="text-align: right;">Page 314</p> <p>1 understanding of what it was doing and how it was 2 formed?</p> <p>3 A. Well, USP has the Council of Experts, 4 which has many expert committees. But the expert 5 committees have the possibility of forming 6 subcommittees, drawing on expertise from different 7 committees. So I see a subcommittee being formed 8 jointly from several expert committees to consider 9 particularly the topic of nitrosamines in 10 small-molecule medicines.</p> <p>11 Q. To your knowledge, did the USP 12 Nitrosamines Joint Subcommittee exist before 2018?</p> <p>13 A. I don't know that. As far as I know, it 14 didn't exist.</p> <p>15 Q. All right. So if you turn to page 4, I 16 believe you were asked to read some of the text on 17 this page, and you were asked if you agreed with it. 18 Do you remember that?</p> <p>19 A. Page 4. Is this the one down at the 20 bottom where he's talking about the grilled burger?</p> <p>21 Q. Let me see. I know the pages aren't 22 numbered, which makes it difficult, but I'm just 23 counting three, four.</p> <p>24 A. Oh, okay. All right. Thank you.</p> <p>25 Q. Okay. So the very last paragraph on</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. And if you skip down, midway on the page 2 Edwin Gump is speaking.</p> <p>3 A. He is.</p> <p>4 Q. He says, "It's a good question. So, one 5 of the things that I think the pharmaceutical 6 industry has generally for the most part done very 7 well is look at impurities." Do you agree with 8 that?</p> <p>9 A. I do.</p> <p>10 Q. He goes on to say, "I think nitrosamines, 11 for the reasons I just described, are kind of a 12 unique case where they can sort of crop up." Do you 13 agree with that?</p> <p>14 A. I do agree with that.</p> <p>15 Q. He goes on, "They aren't necessarily 16 readily identified as part of the components during 17 the manufacturing process, and so they sort of slip 18 through." Is that your understanding as well?</p> <p>19 A. I think I could agree with that.</p> <p>20 Q. "Whereas, other types of impurities, I 21 think, manufacturers have a" "better handle on how 22 to control those."</p> <p>23 A. Yes, I think he is speaking to what I was 24 trying to comment on as well, that there are sort of 25 general ways of dealing with impurities, but the</p>
<p style="text-align: right;">Page 315</p> <p>1 page 4, that begins, "So, and again"; do you see 2 that?</p> <p>3 A. Yes, I do see that.</p> <p>4 Q. Oh, good. Can you read that paragraph as 5 well?</p> <p>6 A. "So, and again, I think I mentioned, we're 7 talking about really ultratrace levels, parts per 8 million, part per billion. So, these are not easy 9 analyses to perform. They require highly complex 10 analytical equipment, and with any test, you need to 11 kind of have what's the control to that test."</p> <p>12 Q. So do you agree with that statement?</p> <p>13 A. I certainly do.</p> <p>14 Q. And if you look at the following page, 15 first paragraph.</p> <p>16 A. Yes, and I can read it, but I think what 17 USP is doing is talking about its reference 18 materials, and they are talking about reference 19 materials for nitrosamine impurities.</p> <p>20 Q. And in Paragraph 2 it says, "So, having 21 the reference standards is a really important tool 22 for manufacturers."</p> <p>23 A. Yeah.</p> <p>24 Q. Did I read that correctly?</p> <p>25 A. Yes, that's quite true.</p>	<p style="text-align: right;">Page 317</p> <p>1 nitrosamine impurities are -- as FDA said, are very 2 unusual, unexpected. You have to think that they 3 may be there, and then even when you think that, 4 they are at very low levels and require very special 5 techniques to measure.</p> <p>6 Q. So towards the bottom of the page, 7 finally, Mr. Gump is saying, "It really is, I think, 8 a lot better than people think. You tend to hear 9 about the few problems that occur, but you don't 10 hear about the millions or billions of pills that 11 get distributed every year and help people deal with 12 their health conditions." Do you agree with that 13 sentiment?</p> <p>14 A. I can certainly attest to that.</p> <p>15 Q. So, Dr. Williams, you know, just to be 16 clear for the record, you weren't really asked much 17 about your report and your opinions in it. But have 18 you heard anything today that causes you to change 19 your opinions as stated in your expert report?</p> <p>20 MR. STANOCH: Objection to form.</p> <p>21 THE WITNESS: No, nothing at all.</p> <p>22 BY MS. LOCKARD:</p> <p>23 Q. Have you been shown any documents today or 24 testimony that changes your opinion in any way?</p> <p>25 A. No.</p>

<p>1 Q. So in terms of, really, if we can get to 2 the heart of your opinions, what are your core 3 opinions in this case?</p> <p>4 MR. STANOCH: Objection.</p> <p>5 THE WITNESS: You know, the way I would 6 summarize those, I think they appear in the last 7 page or two of my report, and I'll try to say it 8 this way.</p> <p>9 Teva's products, all four 10 valsartan-containing drug products were always 11 pharmaceutically equivalent and bioequivalent to the 12 Diovan reference listed drugs made by Novartis. 13 While they were in the market, they were always 14 AB-rated by FDA. They were not misbranded because 15 FDA required them to have substantively the same 16 label as Diovan.</p> <p>17 And they were not adulterated in my view 18 until -- and you could even debate it after that 19 point, but they certainly were not adulterated or 20 defective until FDA issued warning letters to ZHP 21 and Mylan or when FDA set limits in December of 22 2019.</p> <p>23 So what you have -- and I said it in the 24 report, it's a very unusual situation, where we all 25 know nitrosamine impurities can be genotoxic. We</p>	<p>Page 318</p> <p>1 that Teva did anything wrong and everything right. 2 MS. LOCKARD: I don't have any more 3 questions for you at this time. I imagine there may 4 be more questions. Thank you, Dr. Williams. And I 5 may follow up.</p> <p>6 EXAMINATION</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Dr. Williams, prior to your 9 question-and-answer session with Ms. Lockard, you 10 spoke with her during the lengthy 35-minute break, 11 didn't you?</p> <p>12 MS. LOCKARD: Object to form.</p> <p>13 Argumentative.</p> <p>14 THE WITNESS: I would say I sat there and 15 listened to her talk out how she was going to 16 question me, but I really didn't engage in that 17 discussion in any substantive way.</p> <p>18 MR. STANOCH: Stand by.</p> <p>19 Nothing further, Doctor.</p> <p>20 MS. LOCKARD: Any other questions from 21 others?</p> <p>22 MR. STANOCH: And, Counsel, I'll just ask 23 on the record that the binder of potential exhibits 24 be destroyed or returned to me without looking at 25 it, please.</p>
<p>Page 319</p> <p>1 know they are very low level. They are hard to 2 measure. They can creep into a product, as Dr. Gump 3 said.</p> <p>4 And FDA and Teva in the summer of '22 5 (verbatim) were faced with this issue. Well, we 6 have got them there. What are we going to do? And 7 FDA and Teva working together decided to recall, 8 first, all the ZHP products from the market before 9 there was any possibility of a decision about 10 adulteration, and then subsequently, after the 11 Swissmedic report, all the Mylan product from the 12 market, again, before there was any possibility of a 13 decision about adulteration.</p> <p>14 As I said in the report, this is not a 15 failure. This is a success story where a 16 responsible company is making a huge effort to 17 protect consumers, to protect patients, and FDA is 18 working very hard to find out what is going on.</p> <p>19 It spills over into other products. It 20 keeps spilling over into other products. And now 21 FDA is asking that essentially all chemical 22 medicines in the market or being developed for the 23 market be assessed for nitrosamine impurities.</p> <p>24 I'm gratified with the effort. This is 25 how drug regulation advances. And I just don't see</p>	<p>Page 320</p> <p>1 MS. LOCKARD: All right. I did take the 2 exhibits you used out of the binder.</p> <p>3 MR. STANOCH: That's fair. I understand.</p> <p>4 Thank you.</p> <p>5 MS. LOCKARD: I'll put them back. But I 6 didn't remove the ones that you haven't used and I 7 haven't looked at all of those, so --</p> <p>8 MR. STANOCH: I appreciate that. Thank 9 you, Counsel.</p> <p>10 THE VIDEOGRAPHER: Anything further on the 11 record?</p> <p>12 Okay. Well, this concludes today's 13 deposition of Dr. Roger Williams. We are going off 14 the record at 4:24.</p> <p>15 (Whereupon, the deposition was concluded 16 at 4:24 p.m.)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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